ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-K
March 08, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO

SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended December 31, 2005

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____

Commission file number: 001-15989

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4022871**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

100 Endo Boulevard

Chadds Ford, Pennsylvania 19317

(Address of Principal Executive Offices)

(Registrant s Telephone Number, Including Area Code): (610) 558-9800

Securities registered pursuant to Section 12(b) of the Act: N/A

Securities registered pursuant to Section 12(g) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock	**NASDAQ**

Annual Report for the Year Ended December 31, 2005

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ¨ NO þ

Indicate by check whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No ¨

Indicate by check if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer þ Accelerated filer ¨ Non-accelerated filer ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ¨ NO þ

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant s most recently completed second fiscal quarter (June 30, 2005): $1,776,590,914 based on the last reported sale price on the NASDAQ on June 30, 2005.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of March 1, 2006: 132,922,980.

Documents Incorporated by Reference

Portions of the registrant s proxy statement to be filed with the SEC pursuant to Regulation 14A in connection with the registrant s 2006 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant s fiscal year ended December 31, 2005.

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FORWARD LOOKING STATEMENTS

This document contains information that includes or is based on forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements, including estimates of future net sales, future net income and future earnings per share, contained in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations, which is included in documents incorporated by reference, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Item 1A Risk Factors in this document, supplement, and as otherwise enumerated herein, could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in this document. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this document include those factors described in this document under Item 1A titled Risk Factors, including, among others:

- our ability to successfully develop, commercialize and market new products;
- timing and results of pre-clinical or clinical trials on new products;
- our ability to obtain regulatory approval of any of our pipeline products;
- competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;
- significant cash payments we may be required to make to Endo Pharma LLC pursuant to a tax sharing agreement;
- market acceptance of our future products;
- government regulation of the pharmaceutical industry;
- our dependence on a small number of products;
- our dependence on outside manufacturers for the manufacture of our products;
- our dependence on third parties to supply raw materials and to provide services for certain core aspects of our business;
- new regulatory action or lawsuits relating to our use of narcotics in most of our core products;

our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;

our ability to protect our proprietary technology;

the successful efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products;

our ability to successfully implement our acquisition and in-licensing strategy;

regulatory or other limits on the availability of controlled substances that constitute the active ingredients of some of our products and products in development;

the availability of third-party reimbursement for our products;

the outcome of any pending or future litigation or claims by the government; and

our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales.

We do not undertake any obligation to update our forward-looking statements after the date of this Report for any reason, even if new information becomes available or other events occur in the future. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q and 8-K reports to the SEC.

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PART I

Item 1. ***Business***

Overview

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. We have one reportable segment, pharmaceutical products. According to Wolters Kluwer Health data (formerly NDC Health), the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $18.7 billion in 2005. This represents an approximately 6% compounded annual growth rate since 2001. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2005, analgesics were the fourth most prescribed medication in the United States with over 246 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 89% of the U.S. analgesics prescriptions for 2005. Total U.S. sales for the opioid analgesic segment were $8.2 billion in 2005, representing a compounded annual growth rate of 10% since 2001.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Frova®, Percodan® and DepoDur®. Branded products comprised approximately 71% of our net sales in 2005, with 51% of our net sales coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 29% of net sales in 2005, currently consists of products primarily focused in pain management, with our generic oxycodone extended-release tablets accounting for 14% of our net sales in 2005. We focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded product pipeline includes two filed New Drug Applications, or NDAs, three products in Phase III clinical trials and four products in Phase II clinical trials.

We enhance our financial flexibility by outsourcing certain of our functions, including manufacturing. Currently, our primary suppliers of contract manufacturing services are Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd.

Through a dedicated sales force of approximately 370 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

On a continuous basis, we evaluate and, where appropriate, pursue acquisition and licensing opportunities on terms we consider favorable. In particular, we look to continue to enrich our product line by acquiring or licensing rights to additional products and compounds and therefore regularly evaluate selective acquisition and license opportunities. Such acquisitions or licenses may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. Currently, however, we have no binding commitment related to any acquisitions or licenses.

Our wholly owned subsidiary, Endo Pharmaceuticals Inc., commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became DuPont Pharmaceuticals Company and was thereafter purchased by the Bristol Myers Squibb Pharma Company in 2001. Endo Pharmaceuticals Inc. was formed by some members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement, under which we acquired these initial assets.

We were incorporated in Delaware as a holding company on November 18, 1997 and have our principal executive offices at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317 (telephone number: (610) 558-9800).

Our Strategy

Our business strategy is to continue to strengthen our position as a market leader in pain management while also pursuing other markets, especially those with complementary therapeutic or physician bases. The elements of our strategy include:

Capitalizing on our established brand names and brand awareness through focused marketing and promotional efforts. Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, continues to increase market penetration due to our ongoing promotional and educational efforts. We consider two of our brands, Percocet® and Percodan®, to be

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gold standards of pain management. Percocet® has been prescribed by physicians since 1976, while Percodan® has been prescribed since 1950. We believe that we have established credibility with physicians as a result of these products history of demonstrated effectiveness and safety. We plan to continue to capitalize on this brand awareness to market new products and explore new indications for existing products. During 2004, we launched Frova®, which we believe has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported recurrence rate in its clinical program. We believe these distinct characteristics have yet to be fully exploited in the North American market and that we will be able to capitalize on Frova® s clinical benefits and commercial potential by targeting the specialty physician audience and effectively leveraging the relationships and reputation that we have built with the neurology and pain specialist community over the years. During 2004, we began our educational efforts to physicians including advocacy development for DepoDur®, the first and only single-dose epidural injection that can provide up to 48 hours of pain control to help ease pain for people undergoing major surgery in the United States. We began promoting DepoDur® in early 2005 with its 70-representative hospital sales force. The launch phase of this product is expected to continue throughout 2006. We believe that our strong corporate and product reputation leads to more rapid adoption of our new products by physicians.

Leveraging our pain management expertise by developing proprietary products and generic products with significant barriers to market entry. To capitalize on our expertise in pain management, we are developing new products to address acute, chronic and neuropathic pain conditions. Specifically, we are developing new patent-protected products that may substantially improve the treatment of pain. We are co-developing an oral extended-release (ER) version of oxymorphone with Penwest Pharmaceuticals Co. and are internally developing an oral immediate-release (IR) version of oxymorphone. On December 22, 2005, we filed complete responses to the U.S. Food and Drug Administration s approvable letters on the company s New Drug Applications (NDAs) for each of its investigational products oxymorphone extended-release (oxymorphone ER) and immediate-release (oxymorphone IR) tablets. As previously disclosed on October 20, 2003, the FDA issued approvable letters for oxymorphone ER and IR tablets but had requested that we address certain questions and provide more clarification and information, including data from additional clinical trials to further confirm the safety and efficacy of these products. Under the Prescription Drug User Fee Act (PDUFA) guidelines, the FDA confirmed our six-month PDUFA date as June 22, 2006, which is the date on which we expect to receive action letters from the FDA on these filings. If approved, we expect to launch oxymorphone ER and IR in the second half of 2006. Oxymorphone ER would compete in the market for long-acting, strong opioids. In order to meet the FDA s request for more clinical information for oxymorphone ER, we conducted two separate multi-center, randomized, double-blind, placebo-controlled, 12-week, parallel group trials evaluating this product in two distinct groups of patients with chronic low back pain: opioid-naive and opioid-experienced. These trials demonstrated statistically ($p<0.0001$) and clinically significant efficacy in these patient populations. The trial involving opioid-naive patients was conducted under the FDA s Special Protocol Assessment (SPA) process. We also reported that the complete response to the oxymorphone IR approvable letter included previously disclosed positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. Endo also conducted this study under the FDA s SPA process. The data from the two new oxymorphone ER Phase III studies and from the one oxymorphone IR Phase III study will supplement the previously submitted Phase III trials for both products that the company believes the FDA already has accepted as demonstrating efficacy in the intended patient populations.

On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo s favor by the U.S. District Court for the Southern District of New York on January 5, 2004, which found Purdue had committed inequitable conduct in the U.S. Patent and Trademark Office. This affirmance by the Federal Circuit Court dismissed the claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoined Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue s petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. On February 1, 2006, we announced that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. We intend to continue marketing our generic oxycodone extended-release tablets at this time. In the event there is a final nonappealable judgment that Purdue s patents are valid and enforceable, we could face substantial liability for patent infringement and be obligated to pay Purdue damages in an amount to be determined by the District Court. Although there can be no assurance, we believe that we would be able to fund the payment of these damages without materially adversely affecting our business operations, including our acquisition and licensing strategy. See Item 3. Legal Proceedings for further information. The U.S. Food and Drug Administration had previously granted final approval of our abbreviated new drug application (ANDA) for all four strengths of this product in 2004. Our oxycodone extended-release tablets are AB-rated bioequivalent versions of OxyContin®, a

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product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. All OxyContin® strengths, as well as generics of all strengths, had combined 2005 U.S. sales of approximately $1.8 billion. We launched all four strengths of the product on June 7, 2005 and had net sales of $114.0 million for the year ended December 31, 2005.

Acquiring and in-licensing complementary products, compounds and technologies. We look to continue to enrich our product line through selective product acquisitions and in-licensing, or acquiring licenses to products, compounds and technologies from third parties. In August 2004, we entered into a license agreement with Vernalis Development Limited (Vernalis), under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. Frova® is being studied for a potential new indication the prevention of menstrual migraine headaches and for which the second pivotal Phase III trial has now completed enrollment. In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl are believed to include both a fast onset of action and patient convenience. In 2005, Rapinyl advanced into Phase III clinical trials. In March 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and available in the U.S. only in oral form. Also in March 2005, we entered into an agreement that will give us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada. The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven (7) days. In January 2006, we licensed in Synera, an FDA-approved topical local anesthetic patch for which we acquired the exclusive North American marketing rights. We expect to launch Synera in the second half of 2006.

Our Competitive Strengths

We believe that we have established a position as a market leader among specialty pharmaceutical companies by capitalizing on our following core strengths:

Established portfolio of branded products. We have assembled a portfolio of branded pharmaceutical products to treat and manage pain. These products include Lidoderm®, a topical patch containing lidocaine, which is the first FDA-approved product to treat the pain associated with post-herpetic neuralgia. The FDA has granted Lidoderm® orphan drug status, which means, generally, that no other lidocaine-containing topical patch product can be approved for this indication until March 19, 2006. Additionally, Lidoderm® is protected by certain patents until 2015. Net sales of Lidoderm® increased 36% from $309.2 million in 2004 to $419.4 million in 2005. We consider Percocet®, our oxycodone/acetaminophen combination product, and Percodan®, our oxycodone/aspirin combination product, which have been marketed since 1976 and 1950, respectively, to be gold standards of pain management based on their long history of demonstrated product safety and effectiveness. Net sales of Percocet® were $110.7 million for the twelve months ended December 31, 2005 compared with $86.5 million in the same period in 2004. We believe our close relationships with physicians who are considered to be pain management thought leaders in pain centers, hospitals, and other pain management institutions enable us to continue our market penetration. During 2004, we added Frova® to our portfolio of branded products, which we believe has differentiating features from other migraine products, including the longest half-life in the triptan class and a very low reported recurrence rate in its clinical program. We believe these distinct characteristics have yet to be fully exploited in the North American market and that we will be able to capitalize on Frova® s clinical benefits and commercial potential by targeting the specialty physician audience and effectively leveraging the relationships and reputation that we have built with the neurology and pain specialist community over the years. Net sales of Frova® were $38.1 million for the twelve months ended December 31, 2005 compared with $11.4 million in 2004, after its commercial launch by Endo in August 2004. We believe this interaction with the thought leaders and our track record of developing and launching new products has enabled us to pursue, through in-licensing and acquisitions, novel products for the treatment of pain and complementary therapeutic areas.

Substantial pipeline focused on pain management with a balanced focus on complementary therapeutic areas. As a result of our focused research and development efforts, we filed two NDAs with the FDA in December 2002 for oxymorphone ER tablets and oxymorphone IR tablets. On December 22, 2005, we filed complete responses to the U.S. Food and Drug Administration s approvable letters on the company s New Drug Applications (NDAs) for each of its investigational products oxymorphone extended-release (oxymorphone ER) and immediate-release (oxymorphone IR) tablets. As previously disclosed on October 20, 2003, the FDA issued approvable letters for oxymorphone ER and IR tablets but had requested that we address certain questions and provide more clarification and information, including data from additional clinical trials to further confirm the safety and efficacy of these products. Under PDUFA guidelines, the FDA confirmed our six-month PDUFA date as June 22, 2006, which is the date on which we expect to

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receive action letters from the FDA on these filings. If approved, we expect to launch oxymorphone ER and IR in the second half of 2006. Oxymorphone ER would compete in the market for long-acting, strong opioids. In order to meet the FDA s request for more clinical information for oxymorphone ER, we conducted two separate multi-center, randomized, double-blind, placebo-controlled, 12-week, parallel group trials evaluating this product in two distinct groups of patients with chronic low back pain: opioid-naive and opioid-experienced. These trials demonstrated statistically ($p<0.0001$) and clinically significant efficacy in these patient populations. The trial involving opioid-naive patients was conducted under the FDA s Special Protocol Assessment (SPA) process. We also reported that the complete response to the oxymorphone IR approvable letter included previously disclosed positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. Endo also conducted this study under the FDA s SPA process. The data from the two new oxymorphone ER Phase III studies and from the one oxymorphone IR Phase III study will supplement the previously submitted Phase III trials for both products that the company believes the FDA already has accepted as demonstrating efficacy in the intended patient populations. In addition, we currently have three products in Phase III clinical trials and four products in Phase II clinical trials.

Research and development expertise. Our research and development effort is focused on expanding our product portfolio by capitalizing on our core expertise with analgesics. We have assembled an experienced and multi-disciplined research and development team of scientists and technicians with a proven expertise working with analgesics and complex formulations. We believe this expertise allows for timely FDA approval of our products. We have demonstrated our ability to commercialize our research and development efforts during the last seven years through the launch of a number of new products and product line extensions since August 1997.

Targeted national sales and marketing infrastructure. We market our products directly to physicians through an internal sales force of approximately 300 specialty and office-based representatives and approximately 70 hospital-based representatives. Through our sales force, we market our branded pharmaceutical products to just over 44,000 physicians, which include both specialists and primary care physicians.

Selective focus on generic products. Our generic product portfolio includes products focused on pain management. Development of these products involves barriers to entry such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing. We believe products with these characteristics will face a lesser degree of competition and therefore provide longer product life cycles and higher profitability than commodity generic products. We have executed our generic product development strategy successfully to date with products such as morphine sulfate extended-release tablets, which we introduced in November 1998 as a bioequivalent version of MS Contin, a product of The Purdue Frederick Company. In addition, on June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo s favor by the U.S. District Court for the Southern District of New York on January 5, 2004, which found Purdue had committed inequitable conduct in the U.S. Patent and Trademark Office. This affirmance by the Federal Circuit Court dismissed the claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoined Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue s petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. On February 1, 2006, we announced that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same district court for its further consideration as to whether the Purdue patents are unenforceable. We intend to continue marketing our generic oxycodone extended-release tablets at this time. In the event there is a final nonappealable judgment that Purdue s patents are valid and enforceable, we could face substantial liability for patent infringement and be obligated to pay Purdue damages in an amount to be determined by the District Court. Although there can be no assurance, we believe that we would be able to fund the payment of these damages without materially adversely affecting our business operations, including our acquisition and licensing strategy. See Item 3. Legal Proceedings for further information. The U.S. Food and Drug Administration had previously granted final approval of our abbreviated new drug application (ANDA) for all four strengths of this product in 2004. Our oxycodone extended-release tablets are AB-rated bioequivalent versions of OxyContin®, a product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. All OxyContin® strengths, as well as generics of all strengths, had combined 2005 U.S. sales of approximately $1.8 billion. We launched all four strengths of the product on June 7, 2005 and had net sales of $114.0 million for the year ended December 31, 2005.

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Experienced and dedicated management team. Our senior management team has a proven track record of building our business through internal growth as well as through acquisitions and licensing. Members of our senior management led the purchase of the company from The DuPont Merck Pharmaceutical Company in August 1997 as well as the licensing of Lidoderm®, CHRONOGESIC, DepoDur®, Propofol IDD-D, Frova®, Rapinyl and Synera, which is an FDA-approved topical local anesthetic patch as well as two other products, a topical ketoprofen patch being studied for soft tissue injuries, a 7-day transdermal sufentanil patch being studied for moderate to severe chronic pain. Management has received FDA approval on more than fifteen new products and product line extensions since 1997, and as a result of several successful product launches, has grown our net sales from approximately $108.4 million in 1998 to approximately $820.2 million in 2005.

Our Industry

According to Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $18.7 billion in 2005. This represents an approximately 6% compounded annual growth rate since 2001. Our primary area of focus within this market is analgesics. In 2005, analgesics were the fourth most prescribed medication in the United States with over 246 million prescriptions written for this classification. These products are used primarily for the treatment of pain associated with orthopedic fractures and sprains, back injuries, migraines, joint diseases, cancer and various surgical procedures.

Opioid analgesics comprised approximately 89% of the U.S. analgesics prescriptions in 2005. This market segment has grown to $8.2 billion in 2005, representing a compounded annual growth rate of 10% since 2001. If branded products were substituted for generic products, we believe the dollar value of this market segment would be substantially larger. The growth in this segment has been primarily attributable to:

- increasing physician recognition of the need and patient demand for effective treatment of pain;
- aging population (according to the U.S. Census Bureau, in 2000 the population aged 65 and older reached 35 million people and is expected to grow to 40 million people by 2010, representing 14% growth over this period);
- introduction of new and reformulated branded products; and
- increasing incidence of chronic pain conditions, such as cancer, arthritis and low back pain.

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Product Overview

The following table summarizes select products in our marketed portfolio as well as selected products in development:

Product	Active ingredient(s)	Branding	Status
Lidoderm®	lidocaine 5%	Branded	Marketed
Percocet®	oxycodone and acetaminophen	Branded	Marketed
Percodan®	oxycodone and aspirin	Branded	Marketed
Frova®(1)	frovatriptan	Branded	Marketed
DepoDur®(2)	morphine sulfate	Branded	Marketed
Endocet®	oxycodone and acetaminophen	Generic	Marketed
Morphine Sulfate ER	morphine sulfate	Generic	Marketed
Oxycodone ER	oxycodone hydrochloride	Generic	Marketed
Synera™ (3)	lidocaine and tetracaine	Branded	FDA approved
Oxymorphone ER(4)	oxymorphone hydrochloride	Branded	PDUFA date June 22, 2006
Oxymorphone IR	oxymorphone hydrochloride	Branded	PDUFA date June 22, 2006
Frova® (menstrual migraine)(1)	frovatriptan	Branded	Phase III
Rapinyl (oral, fast dissolving)(5)	fentanyl	Branded	Phase III
Synera™ (3) (new indication)	lidocaine and tetracaine	Branded	Phase III
Topical Ketoprofen Patch(6)	ketoprofen	Branded	Phase II
Lidoderm® (new indications)	lidocaine 5%	Branded	Phase II
LidoPAIN® BP(7)	lidocaine	Branded	Phase II
Propofol IDD-D(2)	propofol	Branded	End of Phase II
CHRONOGESIC(8)	sufentanil	Branded	Early Stage
Transdermal Sufentanil Patch(9)	sufentanil	Branded	Early stage

(1) Licensed marketing rights from Vernalis Development Limited.

(2) Licensed marketing rights from SkyePharma, Inc.

(3) Licensed marketing rights from ZARS Pharma

(4) Co-developed with Penwest Pharmaceuticals Co.

(5) Licensed marketing and development rights from Orexo AB.

(6) Licensed marketing and development rights from ProEthic Pharmaceuticals, Inc.

(7) Licensed marketing rights from EpiCept Corporation.

(8) Licensed marketing rights from DURECT Corporation.

(9) Licensed marketing and development rights from DURECT Corporation.

Branded Products

Lidoderm®. Lidoderm® was launched in September 1999. A topical patch product containing lidocaine, it is the first FDA-approved product for the relief of the pain associated with post-herpetic neuralgia. There are approximately 200,000 patients per year who suffer from this condition in the United States, the majority of whom are elderly. The FDA has granted Lidoderm® orphan drug status, generally meaning that no other lidocaine-containing topical patch product can be approved for this indication until March 19, 2006. Certain exceptions apply (for example, a product shown to be clinically superior may be approved); however, we are unaware that any such product has been, or is being, developed. Lidoderm® is also currently protected by patents for, among other things, a method of treating post-herpetic neuralgia and the composition of the lidocaine-containing patch. The last of these patents will expire in 2015. In 2005, 2004 and 2003, Lidoderm® net sales were $419.4 million, $309.2 million and $178.3. million, respectively. Lidoderm® accounted for approximately 51% of our 2005 net sales.

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In addition, we are currently exploring potential new indications for Lidoderm® and have initiated Phase II clinical trials.

Percocet®. We consider Percocet® to be a gold standard of pain management. Launched in 1976, Percocet® is approved for the treatment of moderate-to-moderately severe pain. The Percocet® family of products had net sales of $110.7 million, $86.5 million and $214.2 million in the years 2005, 2004 and 2003, respectively. The Percocet® franchise accounted for approximately 13% of our 2005 net sales.

Frova®. We began shipping Frova® upon closing of the license agreement with Vernalis in mid-August 2004 and initiated our promotional efforts in September 2004. We believe that Frova® has differentiating features from other migraine products, including the longest half life in the triptan class and a very low reported recurrence rate in its clinical program. We believe these distinct characteristics have yet to be fully exploited in the North American market and that we will be able to capitalize on Frova® s clinical benefits and commercial potential by targeting the specialty physician audience and effectively leveraging the relationships and reputation that Endo has built with the neurology and pain specialist community over the years. We believe we can create an advocacy base among thought leaders who treat patients with the most intractable migraines. In addition,, Frova® is being studied for the prevention of menstrual migraine. Net sales of Frova® were $38.1 million in 2005 and $11.4 million for the period August 2004, when we began to market the product, to December 2004.

DepoDur®. DepoDur® became available when we began commercial shipments of the product in December of 2004. No revenue was recognized on this product in 2004. Net sales of DepoDur® were $3.9 million for the twelve months ended December 31, 2005. The company began promoting DepoDur® in early 2005 with its 70-representative hospital sales force. The launch phase of this product is expected to continue throughout 2006.

Percodan®. Launched in 1950 for the treatment of moderate-to-moderately severe pain, we also consider Percodan® to be a gold standard of pain management.

Synera. Synera is a topical local anesthetic patch for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the FDA on June 23, 2005, Synera is expected to become commercially available in the second half of 2006. The safety and efficacy of Synera have been demonstrated in a series of clinical trials that included more than 660 pediatric (aged three to 17 years) and adult patients undergoing superficial dermatological procedures. Synera will also be studied for use with additional procedures, such as pediatric immunization.

Other. The balance of our branded portfolio consists of a number of products, none of which accounted for more than 5% of our total net sales in the 2005 fiscal year.

Generic Products

When a branded pharmaceutical product is no longer protected by any relevant patents, normally as a result of a patent s expiration, or by other, non-patent market exclusivity, third parties have an opportunity to introduce generic counterparts to such branded product. Generic pharmaceutical products are therapeutically equivalent to their brand-name counterparts and are generally sold at prices significantly less than the branded product. Accordingly, generic pharmaceuticals may provide a safe, effective and cost-effective alternative to users of branded products.

On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo s favor by the U.S. District Court for the Southern District of New York on January 5, 2004, which found Purdue had committed inequitable conduct in the U.S. Patent and Trademark Office. This affirmance by the Federal Circuit Court dismissed the claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoined Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue s petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. On February 1, 2006, we announced that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. We intend to continue marketing our generic oxycodone extended-release tablets at this time. In

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the event there is a final nonappealable judgment that Purdue s patents are valid and enforceable, we could face substantial liability for patent infringement and be obligated to pay Purdue damages in an amount to be determined by the District Court. Although there can be no assurance, we believe that we would be able to fund the payment of these damages without materially adversely affecting our business operations, including our acquisition and licensing strategy. See Item 3. Legal Proceedings for further information. The U.S. Food and Drug Administration had previously granted final approval of our abbreviated new drug application (ANDA) for all four strengths of this product in 2004. Our oxycodone extended-release tablets are AB-rated bioequivalent versions of OxyContin®, a product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. All OxyContin® strengths, as well as generics of all strengths, had combined 2005 U.S. sales of approximately $1.8 billion. We launched all four strengths of the product on June 7, 2005 and had net sales of $114.0 million for the year ended December 31, 2005.

The remainder of our generic portfolio is currently comprised of products that cover a range of indications, most of which are focused in pain management. One of our generic products is morphine sulfate extended-release tablets, which accounted for 5% of our total net sales in 2005. In addition, we have a generic oxycodone hydrochloride and acetaminophen product, Endocet®, which accounted for 8% of our total net sales in 2005. The balance of our generic portfolio consists of a few other products, none of which accounted for more than 5% of our total net sales for 2005.

We principally pursue the development and marketing of generic pharmaceuticals that have one or more barriers to entry. The characteristics of the products that we may target for generic development may include:

- complex formulation or development characteristics;
- regulatory or legal challenges; or
- difficulty in raw material sourcing.

We believe products with these characteristics will face a lesser degree of competition, therefore providing longer product life cycles and/or higher profitability than commodity generic products.

Products in Development

Our pipeline portfolio contains products intended to address acute pain, chronic pain and neuropathic pain conditions as well as products in complementary therapeutic areas. We cannot predict when or if any of these products will be approved by the FDA.

Oxymorphone ER and IR. On December 22, 2005, we filed complete responses to the U.S. Food and Drug Administration s approvable letters on the company s New Drug Applications (NDAs) for each of its investigational products oxymorphone extended-release (oxymorphone ER) and immediate-release (oxymorphone IR) tablets. As previously disclosed on October 20, 2003, the FDA issued approvable letters for oxymorphone ER and IR tablets but had requested that we address certain questions and provide more clarification and information, including data from additional clinical trials to further confirm the safety and efficacy of these products. Under PDUFA guidelines, the FDA confirmed our six-month PDUFA date as June 22, 2006, which is the date on which we expect to receive action letters from the FDA on these filings. If approved, we expect to launch oxymorphone ER and IR in the second half of 2006. Oxymorphone ER would compete in the market for

long-acting, strong opioids. In order to meet the FDA s request for more clinical information for oxymorphone ER, we conducted two separate multi-center, randomized, double-blind, placebo-controlled, 12-week, parallel group trials evaluating this product in two distinct groups of patients with chronic low back pain: opioid-naive and opioid-experienced. These trials demonstrated statistically ($p<0.0001$) and clinically significant efficacy in these patient populations. The trial involving opioid-naive patients was conducted under the FDA s Special Protocol Assessment (SPA) process. We also reported that the complete response to the oxymorphone IR approvable letter included previously disclosed positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. Endo also conducted this study under the FDA s SPA process. The data from the two new oxymorphone ER Phase III studies and from the one oxymorphone IR Phase III study will supplement the previously submitted Phase III trials for both products that the company believes the FDA already has accepted as demonstrating efficacy in the intended patient populations.

Frova® MM. Currently in Phase III clinical trial development, Frova® is also being studied as a potential prophylactic treatment for menstrual migraine (or MM). If approved for this indication, we believe that Frova® would be the first triptan to be indicated for the prevention of any type of migraine. We anticipate filing a supplemental New Drug Application (sNDA) for this

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indication following the completion by our partner Vernalis of the second of two Phase III clinical trials, for which enrollment is now completed, in the first half of 2006.

Rapinyl. Currently in Phase III clinical trial development, Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. The benefits of Rapinyl are believed to include rapid absorption of the active substance, a fast onset of action and patient convenience, which we believe will improve compliance in cancer patients who experience breakthrough pain. We anticipate being in a position to file the NDA for Rapinyl in the second half of 2007.

Topical Ketoprofen Patch. Currently in Phase II clinical trials in the U.S., the topical ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Following an end of Phase II meeting with the FDA for this development product, we will be initiating the Phase III program in the first half of 2006. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form.

LidoPAIN® BP. Currently in Phase II clinical trial development, LidoPAIN® BP is a patent-protected, adhesive-backed, high-concentration lidocaine-based patch product, intended for the treatment of acute lower back pain. LidoPAIN® BP is being developed by our partner EpiCept.

Propofol IDD-D. Currently at the end of Phase II clinical trial development, Propofol IDD-D is an intravenous, or IV, formulation of propofol as the sole active ingredient using SkyePharma s patented Insoluble Drug Delivery (IDD-D) technology. Propofol IDD-D is being studied by SkyePharma for the maintenance of anesthesia in adults during surgery and for sedation of adults hospitalized in an intensive-care setting. SkyePharma is conducting additional toxicology studies of Propofol IDD-D as required by the FDA to determine the continued viability of the Propofol IDD-D development program.

CHRONOGESIC. Currently in Phase II development, CHRONOGESIC is intended to treat patients with opioid responsive chronic pain that results from a variety of causes. CHRONOGESIC is designed to deliver sufentanil continuously for three months of pain therapy. CHRONOGESIC is a self-driven titanium implant that is placed just under the skin, similar in size to a matchstick, from which drug is released by the natural process of osmosis at a controlled rate. The CHRONOGESIC clinical development program is on temporary hold pending DURECT s implementation of some necessary design and manufacturing enhancements to the CHRONOGESIC product. DURECT anticipates that the implementation of these design and manufacturing enhancements will continue to delay the restart of clinical trials.

Transdermal Sufentanil Patch. The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days.

Other. We also have other undisclosed analgesic products addressing the broad spectrum of pain management in various stages of development.

Competition

The pharmaceutical industry is highly competitive. Our competitors vary depending upon therapeutic and product categories. Competitors include the major brand name and generic manufacturers of pharmaceuticals doing business in the United States, including Abbott Laboratories, Alpharma Inc., Elan Corporation plc, Johnson & Johnson, Ligand Pharmaceuticals Incorporated, Mallinckrodt Inc., Pfizer, Inc., The Purdue Frederick Company, Roxane Laboratories, Inc., Teva Pharmaceutical Industries Ltd., and Watson Pharmaceuticals, Inc.

We compete principally through our targeted product development and acquisition and in-licensing strategies. In addition to product development and acquisition, other competitive factors in the pharmaceutical industry include product quality and price, reputation and access to technical information.

The competitive environment of the branded product business requires us to continually seek out technological innovations and to market our products effectively. However, some of our current branded products not only face competition from other brands, but also from generic versions. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies.

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The entrance of generic competition to one of our branded products generally reduces our market share and adversely affects our profitability and cash flows.

Newly introduced generic products with limited or no other generic competition are typically sold at higher selling prices. As competition from other generic products increases, selling prices of the generic products typically decline. Consequently, the maintenance of profitable operations in generic pharmaceuticals depends, in part, on our ability to select, develop and launch new generic products in a timely and cost efficient manner and to maintain efficient, high quality manufacturing relationships.

We have witnessed a consolidation of our customers as chain drug stores and wholesalers merge or consolidate. In addition, a number of our customers have instituted preferred-source and bundling programs that enhance the access that suppliers who participate in such source programs have to the customers of the wholesaler. Consequently, there is heightened competition among drug companies for the business of this smaller and more selective customer base of chain drug stores and large wholesalers.

Research and Development

We devote significant resources to research and development. At December 31, 2005, our research and development and regulatory affairs staff consisted of 81 employees, primarily based in Westbury, New York and at our corporate headquarters in Chadds Ford, Pennsylvania. For fiscal years 2005, 2004 and 2003, our expenditures on research and development were $88.3 million, $51.5 million and $52.6 million, respectively. In addition to our internal research and development staff, we have agreements and arrangements with various contract research organizations to conduct and coordinate our pre-clinical and clinical studies. In addition, many of the research and development activities of products to which we have licensed the marketing rights are performed by our partners.

Seasonality

Although our business is affected by the purchasing patterns and concentration of our customers, our business is not materially impacted by seasonality.

Major Customers

We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors that, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. Three distributors and one pharmacy chain individually accounted for 31%, 27%, 13% and 3%, respectively, of our net sales in 2005. Three distributors and one pharmacy chain individually accounted for 29%, 18%, 18% and 9%, respectively, of our net sales in 2004. Three distributors and one pharmacy chain individually accounted for 26%, 26%, 19% and 11%, respectively, of our net sales in 2003.

In recent years, there have been numerous mergers and acquisitions among wholesale distributors as well as rapid growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent

drug stores and small drug store chains has decreased. Some wholesale distributors are demanding that pharmaceutical manufacturers, including us, enter into what are referred to as fee-for-service agreements pursuant to which the wholesale distributors provide the pharmaceutical manufacturers with inventory level and other information. To date, we have entered into two such agreements.

Patents, Trademarks, Licenses and Proprietary Property

As of March 3, 2006, we held approximately: 20 U.S. issued patents, 23 U.S. patent applications pending, 56 foreign issued patents, and 96 foreign patent applications pending with respect to our products. In addition, as of March 3, 2006, we have licenses for approximately: 77 U.S. issued patents, 36 U.S. patent applications pending, 168 foreign issued patents and 103 foreign patent applications pending.

The effect of these issued patents is that they provide us with patent protection for the claims covered by the patents. The coverage claimed in a patent application can be significantly reduced before the patent is issued. Accordingly, we do not know whether any of the applications we acquire or license will result in the issuance of patents, or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of 18 months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot

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be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

We believe that our patents, the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all of our intellectual property are important to our business. All of our brand products and certain generic products, such as Endocet® and Endodan®, are sold under trademarks. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. See Licenses and Collaboration Agreements. There can be no assurance that any of our patents, licenses or other intellectual property will afford us any protection from competition.

We rely on confidentiality agreements with our employees, consultants and other parties to protect, among other things, trade secrets and other proprietary technology. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that other third parties will not otherwise gain access to our trade secrets and other intellectual property.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property and to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation. See Item 3. Legal Proceedings.

Governmental Regulation

The manufacture, development, testing, packaging, labeling, distribution, sales and marketing of our products and our ongoing product development activities are subject to extensive and rigorous regulation at both the federal and state levels. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal and state statutes and regulations govern or influence the testing, manufacture, safety, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to enter into supply contracts or to approve NDA and ANDAs, civil sanctions and criminal prosecution.

FDA approval is typically required before each dosage form or strength of any new drug can be marketed. Applications for FDA approval must contain information relating to efficacy, safety, toxicity, pharmacokinetics, product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling, and quality control. The FDA also has the authority to revoke previously granted drug approvals. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial resources.

The current FDA standards of approving new pharmaceutical products are more stringent than those that were applied in the past. These standards were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has recently expressed an intention to develop such databases for certain of these products, including many opioids.

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics, may indicate the potential for having mutagenic effects. If, after testing, such effects are ultimately demonstrated to exist, more stringent controls of the levels of these impurities may be required for FDA approval of products containing these impurities, such as oxymorphone. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary for new or existing products containing such impurities. The FDA s more stringent requirements together with any additional testing or remedial measures that may be necessary could result in increased costs for, or delays in, obtaining approval for certain of our products in development. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless such mutagenic effects are believed to indicate a significant risk to patient health, we cannot make any such assurance.

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We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. Changes could, among other things, require expanded or different labeling, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations. In December 2003, Congress enacted new requirements for testing drug products in children, which may increase the time and cost necessary for new drug development. Congress recently passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition and results of operations.

The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

NDA Process

FDA approval is typically required before any new drug can be marketed. An NDA is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The NDA must contain complete preclinical and clinical safety and efficacy data or a reference to such data. Before the dosing of a new drug in healthy human subjects or patients may begin, stringent government requirements for preclinical data must be satisfied. The preclinical data, typically obtained from studies in animals, as well as from laboratory studies, are submitted in an Investigational New Drug application, or IND, or its equivalent in countries outside the United States where clinical trials are to be conducted. The preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initiation of clinical trials.

Clinical trials are typically conducted in three sequential phases, although the phases may overlap.

- Phase I, which frequently begins with the initial introduction of the compound into healthy human subjects prior to introduction into patients, involves testing the product for safety, adverse effects, dosage, tolerance, absorption, metabolism, excretion and other elements of clinical pharmacology.

- Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.

- Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. In some cases, the FDA allows a company to rely on data developed in foreign countries or previously published data, which eliminates the need to independently repeat some or all of the studies.

Data from preclinical testing and clinical trials are submitted to the FDA in an NDA for marketing approval and to other health authorities as a marketing authorization application. The process of completing clinical trials for a new drug may take several years and require the expenditures of substantial resources. Preparing an NDA or marketing authorization application involves considerable data collection, verification, analysis and expense, and there can be no assurance that approval from the FDA or any other health authority will be granted on a timely basis, if at all. The approval process is affected by a number of factors, primarily the risks and benefits demonstrated in clinical trials as well as the severity of the disease and the availability of alternative treatments. The FDA or other health authorities may deny an NDA or marketing authorization application if the regulatory criteria are not satisfied, or such authorities may require additional testing or information.

As a condition of approval, the FDA or other regulatory authorities may require further studies, including Phase IV post-marketing studies to provide additional data. Other post-marketing studies could be used to gain approval for the use of a product as a treatment

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for clinical indications other than those for which the product was initially tested. Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the adverse effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products.

There is a type of NDA, referred to as a Section 505(b) (2) NDA, that may sometimes be submitted when an applicant does not have a right of reference to all preclinical and clinical data necessary to support an NDA. Section 505(b) (2) NDAs are subject to requirements for patent certifications and notification similar to ANDAs (see next section). Approval of these NDAs also may be delayed by market exclusivity that covers the reference product.

ANDA Process

FDA approval of an ANDA is required before a generic equivalent of an existing or reference-listed drug can be marketed. The ANDA process is abbreviated in that the FDA waives the requirement of conducting complete preclinical and clinical studies and instead relies on bioequivalence studies. Bioequivalence compares the rate of absorption and levels of concentration of a generic drug in the body with those of the previously approved drug. When the rate and extent of absorption of the test and reference drugs are the same, the two drugs are bioequivalent and regarded as therapeutically interchangeable.

An ANDA also may be submitted for a product authorized by approval of an ANDA suitability petition. Such petitions may be submitted to secure authorization to file an ANDA for a product that differs from a previously approved drug in active ingredient, route of administration, dosage form or strength. For example, the FDA has authorized the substitution of acetaminophen for aspirin in certain combination drug products and switching the drug from a capsule to tablet form. Bioequivalence data may be required, if applicable, as in the case of a tablet in place of a capsule, although the two products would not be rated as interchangeable. Congress enacted pediatric testing legislation in December 2002 which may affect pharmaceutical firms ANDA products in the future.

The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the manufacturer of the listed drug is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, the FDA may now extend the exclusivity of a product by six months past the patent expiration date if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension.

The Generic Drug Enforcement Act of 1992, or Generic Act, allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the drug approval process. In some situations, the Generic Act requires the FDA to not accept or review applications for a period of time from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Act allows for civil penalties and withdrawal of previously approved applications. We believe neither we nor any of our employees have ever been subject to debarment.

Patent and Non-Patent Exclusivity Periods

A sponsor of an NDA is required to identify in its application any patent that claims the drug or a use of the drug subject to the application. Upon NDA approval, the FDA lists these patents in a publication referred to as the Orange Book. Any person that files an ANDA to secure approval of a generic version of this first, or listed drug, or a type of NDA that relies upon the data in the application for which the patents are listed, must make a certification in respect to listed patents. The FDA may not approve such an application for the drug until expiration of the listed patents unless (1) the ANDA applicant certifies that the listed patents are invalid, unenforceable or not infringed by the proposed generic drug and gives notice to the holder or the NDA for the listed drug of the bases upon which the patents are challenged, and (2) the holder of the listed drug does not sue the later applicant for patent infringement within 45 days of receipt of notice. Under the current law, if an infringement suit is filed, the FDA may not approve the later application until the earliest of: 30 months after submission; entry of a court judgment holding the patent invalid, unenforceable or not infringed; such time as the court may order; or the patent expires.

One of the key motivators for challenging patents is the 180-day market exclusivity period vis a vis other ANDA applicants granted to the developer of a generic version of a product that is the first to have its ANDA accepted for filing by the FDA and whose filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (a Paragraph IV

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certification) and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s). Given the recent passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the 2003 Medicare Act, with accompanying amendments to the Hatch Waxman Act, this marketing exclusivity would begin to run upon the earlier of the commercial launch of the generic product or upon an appellate court decision in the generic company s favor.

In addition, the holder of the NDA for the listed drug may be entitled to certain non-patent exclusivity during which the FDA cannot approve an application for a competing generic product or 505(b) (2) NDA product. If the listed drug is a new chemical entity, the FDA may not accept any application for five years; if it is not a new chemical entity, the FDA may not approve a competitive application for three years. Certain other periods of exclusivity may be available if the listed drug is indicated for use in a rare disease or is studied for pediatric indications.

Quality Assurance Requirements

The FDA enforces regulations to assure that the methods used in, and facilities and controls used for, the manufacture, processing, packing and holding of drugs conform with current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality, purity and safety characteristics required of them. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the drugs subject to NDAs and ANDAs. If the FDA concludes that the facilities to be used do not meet cGMP, good laboratory practices or GLP or good clinical practices or GCP requirements, it will not approve the application. Corrective actions to remedy the deficiencies must be performed and verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients, or APIs, used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on our business, results of operations and financial condition.

The FDA also conducts periodic inspections of facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations and financial condition. Imported API and other components needed to manufacture our products could be rejected by U.S. Customs. In respect to domestic establishments, the FDA could initiate product seizures or request product recalls and seek to enjoin a product s manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing the company from receiving the necessary licenses to export its products and classifying the company as an unacceptable supplier , thereby disqualifying the company from selling products to federal agencies.

We believe that we and our suppliers and outside manufacturers are currently in compliance with cGMP requirements.

Other FDA Matters

If there are any modifications to an approved drug, including changes in indication, manufacturing process or labeling or a change in a manufacturing facility, an application seeking approval of such changes must be submitted to the FDA or other regulatory authority. Additionally, the FDA regulates post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements. Failure to adhere to such requirements can result in regulatory actions that could have a material adverse effect on our business, results of operations and financial condition.

Drug Enforcement Administration

We sell products that are controlled substances as defined in the Controlled Substances Act, which establishes certain security and record keeping requirements administered by the U.S. Drug Enforcement Administration, or DEA. The DEA is concerned with the control of registered handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I and II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine, sufentanil, fentanyl and hydrocodone, are

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listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

The DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, product launches or, in a case such as oxycodone where the DEA is considering whether the legislation applies, could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position and results of operations.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture or distribute controlled substances must be registered to perform these activities and have the security, control and accounting mechanisms required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

We and our third-party API suppliers, dosage form manufacturers, distributors and researchers have necessary registrations, and we believe all registrants operate in conformity with applicable requirements.

Government Benefit Programs

Statutory and regulatory requirements for Medicaid, Medicare and other government health care programs govern provider reimbursement levels, including requiring that all pharmaceutical companies rebate to individual states a percentage of their net sales arising from Medicaid-reimbursed products. The federal and/or state governments may continue to enact measures in the future aimed at containing or reducing payment levels for prescription pharmaceuticals paid for in whole or in part with government funds. We cannot predict the nature of such measures or their impact on our profitability and cash flows. These efforts could, however, have material consequences for the pharmaceutical industry as a whole and consequently, also for the Company.

On December 8, 2003, President Bush signed into law the Medicare Modernization Act of 2003. The Medicare Modernization Act created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers; the program began in January 2006. This new benefit may result in an increased use of formularies (listings of prescription drugs approved for use) such that, in the event a Medicare beneficiary s medications are not listed on the applicable formulary, such Medicare beneficiary may not receive reimbursement for such medications. Moreover, once these formularies are established, Medicare will not be obligated to pay for drugs omitted from a formulary, and the cost of these non-covered drugs will not be counted towards the $3,600 annual out-of-pocket beneficiary deductible established by the Medicare Modernization Act. Further, beginning in 2006, Medicare prescription drug program beneficiaries are not permitted to purchase private insurance policies, known as Medigap policies, to cover the cost of off-formulary medications. If our products are excluded from these new formularies, demand for our products might decrease, and we may be forced to lower prices for our products, which may adversely affect our business and our results of operations.

Service Agreements

We contract with various third parties to provide certain critical services including manufacturing, warehousing, distribution, customer service, certain financial functions, certain research and development activities and medical affairs.

Third Party Manufacturing, Supply and Other Service Agreements

We contract with various third party manufacturers and suppliers to provide us with our raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Teikoku Seiyaku Pharmaceuticals and Mallinckrodt. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, this may have a material adverse effect on our business, financial condition and results of operations.

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Novartis Consumer Health, Inc.

On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. As of December 31, 2005, we are required to purchase a minimum of $7.8 million of product per year through December 31, 2009. Either party may terminate this agreement on three-years notice, effective at any time after the initial five-year term. In addition, we may terminate this agreement effective prior to the fifth anniversary of the agreement upon three-years notice and the payment of certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

Teikoku Seiyaku Co., Ltd.

Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. The purchase price for the product is equal to a predetermined amount per unit of product. We are required to purchase a minimum of approximately $18 million of product from Teikoku in 2006. The term of this agreement is from November 23, 1998 until the shorter of (1) the expiration of the last to expire patent that is licensed to us from Hind Healthcare Inc. or (2) November 20, 2011. This agreement may be terminated for material breach by either party and by us if the Hind Healthcare license agreement is terminated.

Mallinckrodt Inc.

Under the terms of this agreement, Mallinckrodt manufactures and supplies to us narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. We are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party may terminate this agreement for a material breach.

In addition, under a separate agreement, Mallinckrodt exclusively manufactures and supplies to us a narcotic active drug substance that is not covered under the previously discussed Mallinckrodt agreement. We are required to purchase a fixed percentage of our annual requirements of this narcotic active drug substance from Mallinckrodt. The purchase price of the substance is a fixed amount that may be adjusted annually in the event of Mallinckrodt product cost increases. The current term of this agreement is April 1, 1998 until June 30, 2004, as extended pursuant to an amendment, dated as of May 8, 2000, with an automatic renewal provision for unlimited successive one-year periods, unless terminated by either party. The current renewal term expires on June 30, 2006. This agreement may also be terminated for material breach by either party.

UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.)

Under the terms of this agreement, we appointed UPS Supply Chain Solutions to provide customer service support, chargeback processing, accounts receivables management and warehouse and distribution services for our products in the United States. During the term of this agreement, the UPS personnel responsible for providing our customer service, chargeback processing and accounts receivable management

services may not provide these services to any third party for any third party products that directly compete with our products covered under the agreement. We currently pay UPS (1) a fixed monthly fee for all services and (2) certain out-of-pocket expenses, which, in the aggregate, may, depending on the facts and circumstances at the time, represent material costs to us. For the years ended December 31, 2005, 2004 and 2003, these fees and expenses were approximately $9.7 million, $7.5 million and $6.3 million. The current term of the agreement for all services provided UPS Supply Chain Solutions expires in February 2010. The agreement may be renewed upon mutual agreement of the parties. The agreement may be terminated for material breach and by us, with prior notice: (1) for a sale of our company or a sale of substantially all of our business; (2) for a change in our stock ownership or company control; (3) if we decide to have these services provided in-house or by an affiliate; or (4) if UPS fails to provide additional storage space for our products upon request. In the event of termination under certain circumstances, we are required to pay UPS for certain capital investments and wind-down expenses.

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PPD Development, LP

Under the terms of this agreement, PPD Development, LP has agreed to provide us with clinical development services, business development support and medical information services. We currently pay PPD (1) on a project-by-project basis and (2) certain out-of-pocket expenses, which, in the aggregate, may, depending on the facts and circumstances at the time, represent material costs to us. For the year ended December 31, 2005, these fees and expenses were approximately $5.8 million. The current term of this agreement expires in May 2008, but this agreement automatically renews for successive one year terms unless either party gives written notice not to renew at least three months before the end of the then current term. The agreement may be terminated by either party: (1) upon 90 days written notice without cause; (2) for a material breach upon 30 days prior written notice (provided that the breaching party is given written notice and the opportunity to cure such breach within 30 days); and (3) immediately in connection with bankruptcy. A termination of this agreement does not automatically terminate any ongoing clinical studies PPD may be conducting on our behalf at the time of termination. The agreement calls for certain transition services in the event of termination.

General

In addition to the manufacturing and supply agreements described above, we have an agreement with Kunitz and Associates Inc. to assist with our adverse event reporting as well as agreements with other manufacturers and suppliers. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition and/or results of operations.

Licenses and Collaboration Agreements

We enter into licenses and collaboration agreements to develop, use, market and promote certain of our products from or with other pharmaceutical companies and universities. A description of the material terms of our significant third party collaboration agreements follows:

Penwest Pharmaceuticals

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest s patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER. We had historically shared, on an equal basis, the costs of products developed under this agreement. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we have been and continue to be responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup, from the royalties due to Penwest, the full amount of what Penwest should have contributed had it not exercised such right. Penwest is entitled to receive royalties equal to a percentage beginning at 50%, which could decline to 40% based upon the achievement of certain criteria, of the net realization (as defined in the agreement) of oxymorphone ER. We have exclusive U.S. marketing rights with respect to oxymorphone ER, subject to the terms and conditions contained in this agreement.

Hind Healthcare Inc.

In November 1998, Endo entered into a license agreement (the Hind License Agreement) with Hind Healthcare Inc. (Hind) for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. Under the terms of the Hind License Agreement, Endo paid Hind approximately $10 million (the Hind License Fee) based upon the achievement of certain milestones and capitalized this amount as an intangible asset representing the fair value of these exclusive rights. In addition, Endo pays Hind nonrefundable royalties based on net sales of the product. Royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least $500,000 per year. During 2005, 2004 and 2003, we accrued $46.4 million, $34.5 million and $19.9 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

Lavipharm Laboratories, Inc.

In November 1999, Endo entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which Endo obtained exclusive worldwide rights to Lavipharm s existing drug delivery technology platforms. Under the terms of this collaboration

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agreement, Endo paid an upfront license fee of $1 million. In September 2001, we amended this agreement to limit its scope to one of Lavipharm s existing drug delivery technologies in combination with two specific active drug substances. In January 2004, we terminated this agreement and made a termination payment to Lavipharm of $3 million plus the potential for up to an additional $5 million in contingent termination payments upon the occurrence of future events. The payment of this additional contingent termination amounts is not likely due the fact that U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven s Abbreviated New Drug Application for its developmental transdermal fentanyl patch, as discussed below. We wrote-off the unamortized portion of the upfront license fee and expensed the termination payment of $3 million during the year ended December 31, 2004.

DURECT Corporation

In November 2002, Endo entered into a license agreement (DURECT CHRONOGESIC License Agreement) with DURECT Corporation (DURECT) to develop and commercialize DURECT s CHRONOGESIC (sufentanil) Pain Therapy System for the U.S. and Canada. In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Prior to this amendment, in addition to other specified termination rights provided to both parties, the Agreement provided Endo with a right to terminate the Agreement starting January 1, 2006 in the event that DURECT had not commenced a specified clinical trial for the CHRONOGESIC™ product candidate on or before January 1, 2006, *provided that* Endo provided DURECT written notice of such termination prior to January 31, 2006. Under Amendment No. 3, the foregoing termination right was amended to provide Endo with the right to terminate the Agreement in the event that (i) DURECT had not delivered to Endo on or before March 31, 2007 a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC™ product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT s delivery of the Notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2007. Under Amendment No. 3, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2007. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product candidate in accordance with the terms of the Agreement. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT CHRONOGESIC License Agreement could total up to $52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC . In addition, the DURECT CHRONOGESIC License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT CHRONOGESIC License Agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, the DURECT CHRONOGESIC License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT up to $10.0 million. Finally, in connection with this agreement, on November 8, 2002, Endo purchased approximately 1.5 million common shares of DURECT.

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a $10 million upfront fee that has been expensed as research and development in year ended December 31, 2005, with additional payments of approximately $35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

SkyePharma, Inc.

In December 2002, we entered into a Development and Marketing Strategic Alliance Agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. relating to two of SkyePharma s patented development products, DepoDur® and Propofol IDD-D (collectively, the Skye Products). Under the terms of the Agreement, Endo received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other development products. In return, Endo made a $25 million upfront payment to SkyePharma, which we capitalized as an intangible asset representing the fair value of the exclusive

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license of these distribution and marketing rights. We were amortizing this intangible asset over its useful life of 17 years. During the year ended December 31, 2005, we recorded a receivable from SkyePharma of $5 million based upon the achievement of certain criteria as specified in the agreement. This receivable has been recorded as a reduction to our recorded intangible asset and the intangible asset is now being amortized over its remaining useful life of 15 years. We collected this receivable in January 2006. In addition, SkyePharma may receive additional contingent milestone payments of up to $95 million ($15 million of which has been paid as of December 31, 2005). During the year ended December 31, 2003, we paid and expensed a $5 million milestone payment to SkyePharma upon the acceptance by the FDA of the NDA for DepoDur®. During the year ended December 31, 2004, we paid and expensed a $5 million milestone payment to SkyePharma upon approval of the NDA for DepoDur®. The additional contingent milestone payments also include up to $50 million ($5 million of which has been paid as of December 31, 2005) for Propofol IDD-D , payable when the product successfully achieves certain regulatory milestones, including FDA approval. During the year ended December 31, 2004, we paid and expensed a $5 million milestone payment to SkyePharma upon the advancement of Propofol IDD-D to the end of Phase II clinical development. The total further includes a $15 million milestone payable when net sales of DepoDur® exceed $125 million in a calendar year, and a $20 million milestone payable when net sales of DepoDur® exceed $175 million in a calendar year. SkyePharma will also receive a share of each product s sales revenue that will increase from 20% initially, to a maximum of 60%, of net sales as the Skye Products combined net sales achieve certain thresholds. This agreement provides for the parties to work together to complete the necessary clinical, regulatory and manufacturing work for North American regulatory approval of the Skye Products. SkyePharma will be primarily responsible for clinical development up to final FDA approval, and for the manufacture of the Skye Products, including all associated costs. Upon approval, we will market each Skye Product in the U.S. and Canada, with SkyePharma as the supplier. We are responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses. Under this agreement, we also obtained options on other SkyePharma development products, including DepoBupivicaine , a long-acting, sustained release formulation of the local anesthetic bupivacaine. We had the option to obtain commercialization rights for this product when SkyePharma successfully completes its Phase II trials; however, in February 2006, we relinquished our rights to DepoBupivicaine . In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require us to pay SkyePharma $5.0 million.

Noven Pharmaceuticals, Inc.

In February 2004, we entered into a License Agreement and a Supply Agreement with Noven Pharmaceuticals, Inc. under which Noven exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson s Duragesic® (fentanyl transdermal system). We made an upfront payment of $8.0 million, $1.5 million of which we expensed as research and development costs and $6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We were amortizing this intangible asset over its useful life of 11 years. On September 27, 2005, the U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven s Abbreviated New Drug Application for its developmental transdermal fentanyl patch based on the FDA s assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic®. As a result, we incurred a charge of approximately $4 million related to the write-off of our portion of the transdermal fentanyl patch inventory and an impairment charge of approximately $5.5 million, which represents the unamortized portion of the upfront license fee that we paid Noven in February 2004, during the year ended December 31, 2005. On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

EpiCept Corp.

In December 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. as well as exclusive, worldwide commercialization rights to EpiCept s LidoPAIN® BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept s LidoPAIN® BP product. Under this agreement, we made an upfront payment to EpiCept of $7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of 13 years. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Milestone

payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to $82.5 million. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents expire.

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Vernalis Development Limited

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. Under the terms of the license agreement, we paid Vernalis an upfront fee of $30 million and are required to make anniversary payments for the first two years at $15 million in 2005 and 2006 (the first $15 million anniversary payment was made in 2005), and a $40 million milestone payment upon U.S. Food and Drug Administration, FDA, approval for the menstrual migraine indication (MM). We have capitalized the $30 million up-front payment, the present value of the two $15 million anniversary payments and the difference of $6.2 million between the face amount of the note and its present value at inception (See Note 8 in the attached Consolidated Financial Statements) as an intangible asset representing the fair value of the exclusive license to market Frova®. We are amortizing this intangible asset over its estimated useful life of 15 years. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of $10 million on $200 million in net sales to a milestone of $75 million on $1.2 billion in net sales. These sales milestones could total up to $255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova®. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova® or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova® is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years written notice.

On July 1, 2005, we entered into a co-promotion agreement, as amended on December 22, 2005, with Vernalis. The co-promotion agreement, as amended, is related to the above July 2004 license agreement. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova® in the United States. Vernalis has exercised its co-promotion option, and the co-promotion agreement, as amended, sets forth the certain specific terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the license agreement. Under the terms of both the license and co-promotion agreements, both as amended, we will reimburse Vernalis for certain defined costs of their sales personnel beginning in January 2006.

Orexo AB

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl is based on Orexo s unique patented technology for sublingual administration. This agreement provided for us to make an up-front license fee payment of $10 million, which we capitalized as an intangible asset representing the fair value of the exclusive right to market the product and are amortizing over its estimated useful life of 20 years, in addition to other license fees and payments based on development and regulatory milestones, which may total up to $22.1 million ($7.3 million of which was recorded during the year ended December 31, 2005 and included in research and development expense) through FDA approval of Rapinyl s New Drug Application. The Company expects to pay an additional $5.2 million in 2006. This agreement also provides for royalties upon commercial sales and may include sales milestones if defined sales thresholds are achieved. In addition, this license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the expiration of any market exclusivity right. We can terminate the license agreement under certain circumstances, including upon six months written notice, and we may be required to pay a termination fee of up to $750,000.

ProEthic Pharmaceuticals, Inc.

On March 14, 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, in March 2005, we paid a $10 million upfront fee that has been expensed as research and development during the year ended December 31, 2005, and we could be required to make additional payments of approximately $13.0 million upon the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations,

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warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the tenth (10th) anniversary of the date of the first commercial sale of the product. We can terminate the agreement at any time upon no more than ninety (90) days written notice.

ZARS Pharma

On January 6, 2006, we entered into an agreement with ZARS Pharma for the North American rights to Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical patch. Synera™ is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the U.S. Food and Drug Administration on June 23, 2005, Synera™ is expected to become commercially available in the second half of 2006.

Under the terms of the agreement, we paid ZARS an upfront fee of $11 million which has been capitalized in January 2006 and may be required to make additional payments of up to approximately $27 million upon achievement of certain commercial milestones, $8 million of which will be due upon the first commercial sale of the product, which is expected in the second half of 2006. We will also pay ZARS royalties on our net sales of Synera™.

Other

We have licensed from universities and other companies rights to certain technologies or intellectual property generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from these agreements. These agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

Environmental Matters

Our operations are subject to substantial and evolving federal, state and local environmental laws and regulations concerning, among other matters, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances. We believe that our facilities and the facilities of our third party service providers are in substantial compliance with all provisions of federal, state and local laws concerning the environment and do not believe that future compliance with these provisions will have a material adverse effect on our financial condition or results of operations.

Summary of Recent Transactions

On January 6, 2006, we announced the appointment of John J. Delucca to our Board of Directors. An independent, outside director, Mr. Delucca also has been appointed as a member of the audit committee of the Board of Directors. He replaces Frank J. Loverro, a managing director of Kelso & Company, who has been a member of the Board since July 2000 and who resigned on January 6, 2006. Mr. Delucca, 62, was executive vice president and chief financial officer of the REL Consultancy Group until his retirement in 2004. Prior to that, he served as chief financial officer and executive vice president, finance & administration, of Coty, Inc., from 1999 to 2002. From 1993 to 1999, he was senior vice

president and treasurer of RJR Nabisco, Inc. During his career, he also served in executive positions for Hascoe Associates, Inc., The Lexington Group, the Trump Group, International Controls Corp., and Textron, Inc. Mr. Delucca is currently a non-executive director and chairs the audit committees of ITC Deltacom, Enzo Biochem, Inc. and The Elliot Company. He also serves as a non-executive director and deputy chairman of the audit committee of British Energy PLC.

In January 2006, the Company signed a license agreement with ZARS Pharma that will give it the exclusive North American rights to Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical patch. Under the terms of the agreement, the Company paid ZARS an upfront fee of $11 million, with additional payments of up to approximately $27 million upon achievement of certain commercial milestones, $8 million of which will be due upon the first commercial sale of the product, which is expected in the second half of 2006. The Company will also pay ZARS undisclosed royalties on net sales of Synera™. ZARS is a privately held company based in Salt Lake City, Utah, focused on the development and commercialization of patented technologies that deliver drugs into and across the skin. Synera™ is a topical local anesthetic patch for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the U.S. Food and Drug Administration on June 23, 2005, Synera™ is expected to become commercially available in the second half of 2006.

In January 2006, the Company completed a public offering of 15,000,000 shares of its common stock by certain of its shareholders. All of the shares were already issued and outstanding, except for approximately 40,000 shares representing shares

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underlying outstanding stock options. Endo Pharma LLC sold the majority of the shares being sold. Certain members of management have an ownership interest in Endo Pharma LLC. Shares were sold by management and certain members of the board of directors of the Company. Following completion of the offering, Endo Pharma LLC held approximately 8.0% of Endo s outstanding common stock. The Company did not receive any of the proceeds from this offering.

On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

We have been advised by Brian T. Clingen and Michael W. Mitchell that they each intend to resign from our board of directors effective March 15, 2006, in order to devote more time to their respective current activities. In addition, Michael B. Goldberg and David I. Wahrhaftig, both managing directors of Kelso, have advised us that they also intend to resign from our board of directors on the same date; these resignations are consistent with Kelso s practice of not having its partners serve on the boards of directors of public companies unless Kelso s level of beneficial stock ownership in the company is significant and warrants such participation. Following such resignations, our board of directors will have seven board members, including John J. Delucca who was appointed on January 6, 2006 to replace Endo board member Frank J. Loverro, a managing director of Kelso, who resigned as a board member on that date. In order to ease this transition, we have underway an active process to identify persons qualified to serve as members of our board of directors and may propose such persons for election or appointment in the future.

Description of Credit Facility

In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of $75.0 million. The line of credit expires on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. As of December 31, 2005, we have not borrowed under the credit facility.

Borrowings under the Amended and Restated Credit Agreement bear interest, which is payable at least quarterly, at a rate equal to the bank s floating alternate base rate plus a premium ranging from 0.75% to 1.25%, or at a rate equal to LIBOR plus a premium ranging from 1.75% to 2.25%, depending on the type of borrowing and our performance against certain criteria.

Additionally, fees are charged on the average daily unused amount of the Amended and Restated Credit Agreement at a rate ranging from 0.375% to 0.50% depending on our performance against certain criteria. This commitment fee is payable quarterly.

The Amended and Restated Credit Agreement contains limitations and restrictions concerning, among other things, additional indebtedness, acquisition or disposition of assets, dividend payments and transactions with affiliates. In addition, the Amended and Restated Credit Agreement requires us to maintain certain ratios (as defined therein).

Employees

As of December 31, 2005, we had 710 employees, of which 81 are engaged in research and development and regulatory work, 478 in sales and marketing, 28 in quality assurance and 123 in general and administrative capacities. Our employees are not represented by unions, and we believe that our relations with our employees are good.

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Executive Officers of the Registrant

Set forth below is information regarding each of our current executive officers, as of March 8, 2006:

Name	Age	Position and Offices
Peter A. Lankau	53	President and Chief Executive Officer
Jeffrey R. Black	41	Executive Vice President, Chief Financial Officer and Treasurer
David A.H. Lee, M.D., Ph.D.	56	Executive Vice President, Research & Development and Chief Scientific Officer
Caroline B. Manogue	37	Executive Vice President, Chief Legal Officer and Secretary

PETER A. LANKAU, 53, is President and Chief Executive Officer of Endo and also a member of the Board of Endo. Prior to May 2005, Mr. Lankau was President and Chief Operating Officer of Endo. Prior to April 2003, Mr. Lankau was Senior Vice President, U.S. Business of Endo. Prior to joining Endo in June 2000, Mr. Lankau was Vice President, Sales and Marketing for Alpharma USPD, Inc. in Baltimore, Maryland. He was Vice President, Sales-U.S. Pharmaceuticals for Aventis Pharmaceuticals Inc. (f/k/a Rhone Poulenc Rorer, Inc.) from 1996 to 1999, based in Collegeville, Pennsylvania. Mr. Lankau was Executive Director, Strategy and Development for Aventis from 1995 to 1996. Prior to 1995, he held various management positions at Aventis including business unit management, and had responsibility for Aventis generics business as well as managed care.

JEFFREY R. BLACK, 41, is Executive Vice President, Chief Financial Officer and Treasurer of Endo. Prior to joining Endo in September 1997, Mr. Black became a Partner in June 1997 with Deloitte & Touche LLP in the New York Merger and Acquisition Services Group, after joining that firm in 1986.

DAVID A.H. LEE, M.D. Ph.D., 56, is Executive Vice President, Research & Development and Chief Scientific Officer of Endo. Prior to joining Endo in December of 1997, Dr. Lee was Executive Vice President, Research and Development for CoCensys, Inc., an emerging pharmaceuticals company based in Irvine, California, from 1992 through 1997. Prior to joining CoCensys, Dr. Lee held various positions at Solvay Pharmaceuticals in the Netherlands, ranging from head of global clinical development programs to his final position as Vice President, Research and Development. Dr. Lee received his M.D. and Ph.D. degrees from the University of London and specialized in internal medicine and gastroenterology, prior to joining the pharmaceutical industry.

CAROLINE B. MANOGUE, 37, is Executive Vice President, Chief Legal Officer and Secretary of Endo. Prior to joining Endo in September 2000, Ms. Manogue was an Associate at the law firm Skadden, Arps, Slate, Meagher & Flom LLP since 1995.

We have employment agreements with each of our executive officers.

Dividend Policy

We have never paid cash dividends on our common stock. Furthermore, the payment of cash dividends from earnings is currently restricted by our credit facility. Assuming removal of this restriction, the payment of cash dividends is subject to the discretion of our board of directors and will be dependent on many factors, including our earnings, capital needs and general financial condition. We anticipate that, for the foreseeable future, we will retain our earnings in order to finance the expansion of our business.

Available Information

Our Internet address is http://www.endo.com. The contents of our website are not part of this Annual Report on Form 10-K, and our Internet address is included in this document as an inactive textual reference only. We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission.

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Item 1A. ***Risk Factors***

Risks Related to Our Business

We face intense competition, in particular from companies that develop rival products to our branded products and from companies with which we compete to acquire rights to intellectual property assets.

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully in any of these areas, our business, profitability and cash flows could be adversely affected. Our competitors include many of the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States. In the market for branded pharmaceutical products, our competitors, including Abbott Laboratories, Alpharma Inc., Johnson & Johnson, Ligand Pharmaceuticals Incorporated, Pfizer, Inc. and The Purdue Frederick Company, vary depending on product category, dosage strength and drug-delivery systems. In addition to product safety, development and efficacy, other competitive factors in the branded pharmaceutical market include product quality and price, reputation, service and access to scientific and technical information. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than many of our national competitors in the branded pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

The intensely competitive environment of the branded products business requires an ongoing, extensive search for medical and technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of branded products to healthcare professionals in private practice, group practices and managed care organizations.

Our branded products face competition from generic versions. Generic versions are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to the branded version under third party reimbursement programs, or substituted by pharmacies for branded versions by law. The entrance of generic competition to our branded products generally reduces our market share and adversely affects our profitability and cash flows. Generic competition with our branded products, including Percocet®, has had and will continue to have a material adverse effect on the net sales and profitability of our branded products.

Additionally, we compete to acquire the intellectual property assets that we require to continue to develop and broaden our product range. In addition to our in-house research and development efforts, we seek to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing and joint venture arrangements. Competitors with greater resources may acquire assets that we seek, and even where we are successful, competition may increase the acquisition price of such assets or prevent us from capitalizing on such acquisitions or licensing opportunities. If we fail to compete successfully, our growth may be limited.

If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our branded drugs, our sales may suffer.

The Hatch Waxman Act permits the FDA to approve ANDAs for generic versions of branded drugs. The ANDA process permits competitor companies to obtain marketing approval for a drug with the same active ingredient for the same uses but does not require the conduct and submission of clinical studies demonstrating safety and efficacy for that product. In place of such clinical studies, an ANDA applicant essentially needs only to submit data demonstrating that its product is bioequivalent to the branded product.

The Hatch Waxman Act requires an applicant for a drug that relies, at least in part, on data from the branded drug regarding the safety and efficacy of the same active ingredient, to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we would have 45 days to bring a patent infringement suit in federal district court against the company seeking to violate our patent rights. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the Hatch Waxman Act provides a 30-month stay on the approval of the competitor s application. If the litigation is resolved in favor of the generic applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA s review of the application may be completed. Such litigation is often time-consuming and quite costly and may result in generic competition if such patent(s) are not upheld or if the generic competitor does not infringe such patent(s). The filing of any ANDA in respect to any of our branded drugs, particularly Lidoderm®, could have an adverse impact on our stock price and, if the patents covering our branded drugs, including Lidoderm®, were not upheld in litigation or if the generic competitor is found to not infringe these patents, the resulting generic competition would have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows.

We face intense competition from other manufacturers of generic versions of our generic products.

Our generic products compete with branded products and with generic versions made by or for other manufacturers, such as Mallinckrodt Inc., Roxane Laboratories, Inc., Teva Pharmaceutical Industries Ltd. and Watson Pharmaceuticals, Inc. When additional versions of one of our generic products enter the market, we generally lose market share and our selling prices and margins on the product decline. Because we are smaller than many of our full-line competitors in the generic pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

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On June 7, 2005, we launched the 10mg, 20mg, 40mg and 80mg strengths of our bioequivalent versions of OxyContin®. We had 180 days of marketing exclusivity under the Hatch Waxman Act with respect to the 10mg, 20mg and 40mg strengths of this product, since we were the first applicant to file an ANDA containing a Paragraph IV certification for these oxycodone extended release strengths. After the expiration of our marketing exclusivity period on December 5, 2005, several competitors launched bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin®. Other competitors may launch additional generic versions of all four strengths of OxyContin®. The entrance of other competitors has and will continue to reduce our market share for bioequivalent versions of OxyContin® and adversely affect the profitability of these products.

Most of our net sales come from a small number of products.

Net sales of Lidoderm®, generic oxycodone extended release, Percocet®, Endocet®, and generic morphine sulfate accounted for: 51%, 14%, 13%, 8% and 5%; 50%, 0%, 14%, 19% and 10%; and 30%, 0%, 36%, 11% and 16% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively. The FDA has granted Lidoderm® orphan drug status for the treatment of the pain associated with post herpetic neuralgia, which means, generally, that no other lidocaine containing product can be approved for this indication prior to March 19, 2006. On June 7, 2005, we launched our generic extended release oxycodone product, our bioequivalent, or generic, version of OxyContin®. After the expiration of our marketing exclusivity period in December 2005, several competitors launched bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin®. In addition, we could be forced to stop selling our generic OxyContin® product if the District Court or Federal Circuit Court of Appeals reverses their decisions in our favor and one or more of the Purdue patents are found valid and enforceable and there is a final court decision adverse to us. See We face intense competition from other manufacturers of generic versions of our generic products. and Although we were successful in our patent challenge against Purdue for our generic OxyContin® product, both at trial and on appeal, the Court of Appeals has vacated its unanimous affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. If we are ultimately unsuccessful, we may be liable for damages and the price of our common stock may decline.

If we were unable to continue to market any of these products, if any of them were to lose market share, for example, as the result of the entry of new competitors, particularly from generic versions of branded drugs, or if the prices of any of these products were to decline significantly, our net sales, profitability and cash flows would be materially adversely affected. The introduction of other bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin® has had and will continue to have an adverse effect by reducing our market share and adversely affecting our profitability and cash flows that we would have otherwise achieved if we supplied the exclusive generic equivalent to the 10mg, 20mg and 40mg strengths of OxyContin® and to MS Contin®.

We face intense competition from brand-name companies that sell or license their own generic versions of our generic products or seek to delay the introduction of generic products.

Brand-name pharmaceutical companies have taken aggressive steps to thwart competition from generic equivalents of their brand-name products. In particular, brand-name companies sell directly to the generics market or license their products for sale to the generics market through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called authorized generics). No significant regulatory approvals are required for a brand-name manufacturer to sell directly or through a third party to the generic market. Brand-name manufacturers do not face any other significant barriers to entry into such market. Purdue has permitted Watson Pharmaceuticals Inc. to distribute the so-called authorized generic versions of OxyContin® and MS Contin®, the branded version of our morphine sulfate extended release tablets, pursuant to one or more distribution arrangements with Purdue. The introductions of these so-called authorized generics have had and may continue to have an adverse effect by reducing our market share and adversely affecting our profitability and cash flows.

In addition, brand-name companies continually seek new ways to delay generic introduction and decrease the impact of generic competition, such as filing new patents on drugs whose original patent protection is about to expire; filing an increasing number of patents that are more complex and costly to challenge; filing suits for patent infringement that automatically delay approval by the FDA; developing patented controlled release or other next generation products, which often reduces the demand for the generic version of the existing product for which we may be seeking approval; changing product claims and product labeling; developing and marketing as over-the-counter products those branded products that are about to face generic competition; or filing citizens petitions with the FDA seeking restraints on our products or seeking to prevent them from coming to market. These strategies may increase the costs and risks associated with our efforts to introduce generic products and may delay or prevent such introduction altogether.

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We entered into a tax sharing agreement with Endo Pharma LLC in July 2000, pursuant to which we have made and may continue to make large cash payments to Endo Pharma LLC.

Endo Pharma LLC is a limited liability company that currently holds a significant portion of our common stock, in which affiliates of Kelso & Company and certain members of management have an interest. Endo Pharma LLC was formed in connection with the acquisition of Algos Pharmaceutical Corporation in July 2000 to ensure that the stock options granted pursuant to the Endo Pharma LLC stock option plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Upon the exercise of the stock options granted under the Endo Pharma LLC stock option plans, only currently outstanding shares of our common stock held by Endo Pharma LLC will be received by holders of such options upon exercise.

Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of December 31, 2005, we had recognized compensation deductions of approximately $669 million, which is estimated to result in a tax benefit amount of approximately $257 million). Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of the stock options granted pursuant to the Endo Pharma LLC stock option plans, we entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefit usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of December 31, 2005, approximately 32.7 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Under the tax sharing agreement, we are required to pay approximately $257 million to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

We had no obligation to make any payments under the tax sharing agreement to Endo Pharma LLC prior to the occurrence of a liquidity event. The tax sharing agreement defines a liquidity event as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) primary offerings by us, (ii) secondary sales by Endo Pharma LLC or other holders of common stock or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. On April 30, 2004, we amended the tax sharing agreement to clarify when a liquidity event has occurred and to provide for a specific schedule upon which payments currently contemplated by the tax sharing agreement would be made once a liquidity event has occurred. The amendment established a formula for calculating when a sale of 20% of the common equity of Endo had occurred and specified that secondary sales of Endo common stock include sales pursuant to a shelf registration statement. The amendment also provides that upon the occurrence of a liquidity event, we are obligated to pay to Endo Pharma LLC, within 30 business days, the amount of the tax benefits usable by us in each of the previous taxable years for which we have filed a federal income tax return. Moreover, with respect to all taxable years for which we file our federal income tax return after the occurrence of a liquidity event, the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i) 50% of the estimated amount shall be paid within 15 business days of our receipt from our independent registered public accounting firm of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return.

A liquidity event occurred on August 9, 2004, when Endo Pharma LLC completed the secondary sale of 11 million shares of common stock. The closing of this offering, when combined with the sale by Endo Pharma LLC of the sale of 16.6 million shares on July 8, 2003, constituted a liquidity event under the tax sharing agreement and triggered a payment obligation with respect to tax benefits usable by us in previous years. In 2004, we paid $13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003.

Since 6.6 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offerings on August 9, 2004 and November 29, 2004, at prices of $17.46 and $20.02, respectively, with a weighted average exercise price of $2.44, and an assumed tax rate of 38.7%, we were obligated to pay Endo Pharma LLC a tax benefit of approximately $41 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and other Endo Pharma LLC stock option exercises in 2004, aggregating $21.4 million, was due and was paid within 15 business days of the date we received an opinion on our audited 2004

financial statements from our independent registered public accounting firm and the remaining fifty percent of the tax benefit amount attributable to 2004 was due within 30 business days of the date on which we filed our 2004 tax return with the Internal Revenue Service (which occurred in September 2005) and approximately $21.4 million was paid in October 2005 to satisfy the tax sharing obligations attributable to 2004.

On October 12, 2005, as part of the sale of 33.35 million shares of our common stock, approximately 19.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised at a market price of $26.04, with a weighted average exercise price of $2.72, and an assumed tax rate of 38.4%. Since the attributable compensation charge deductions are usable to reduce our taxes in 2005, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately $175 million, which has been accrued in the fourth quarter of 2005. Fifty percent of the estimated tax benefit amount attributable to the October 12, 2005 offering and any additional tax benefits attributable to

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the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2005 will be due within 15 business days of the date we receive an opinion on our final audited 2005 financial statements from our independent registered public accounting firm and the remaining tax benefit amount attributable to 2005 is due within 30 business days of the date on which we file our 2005 tax return with the Internal Revenue Service.

Additionally, since approximately 2.7 million additional stock options granted under the Endo Pharma LLC stock option plans were exercised prior to January 1, 2006 and since the attributable compensation charge deductions are usable to reduce our taxes in 2005, we will be obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately $26 million in 2006. As a result of the significant tax deductions expected to have been generated in 2005 from the exercise of the 22.2 million stock options discussed above, we have incurred a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of a portion of prior years payments during 2006. All payments that have been, or will be, made or accrued pursuant to the tax sharing agreement have been, or will be, reflected as a reduction of stockholders equity in our consolidated financial statements. As of December 31, 2005, there are approximately 2.8 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of $2.42 per share and an assumed tax rate of 38.4%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was $30.26 per share, the closing price on December 30, 2005, we would generally be able to deduct, for income tax purposes, compensation of approximately $78 million, which could result in a tax benefit amount of approximately $30 million payable to Endo Pharma LLC in 2007 and beyond. Our tax sharing liability as of December 31, 2005 payable to Endo Pharma LLC is approximately $195 million.

Although we were successful in our patent challenge against Purdue for our generic OxyContin® product, both at trial and on appeal, the Court of Appeals has vacated its unanimous affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. If we are ultimately unsuccessful, we may be liable for damages and the price of our common stock may decline.

The Purdue Frederick Company and related parties filed suit against us and our subsidiary, Endo Pharmaceuticals Inc., or EPI, in October 2000 (and again in March 2001 and August 2001) alleging that our 10mg, 20mg, 40mg and 80mg bioequivalent versions of OxyContin®, for which we filed an ANDA, violate three of their patents. The trial of the patent claims concluded in June 2003. The U.S. District Court for the Southern District of New York issued an Opinion and Order on January 5, 2004 holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to Purdue s inequitable conduct. Accordingly, the district court dismissed Purdue s patent infringement suit against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. Purdue filed an appeal as well as motions to stay the injunction against the enforcement of their patents pending the outcome of the appeal and to expedite the appeal. Both motions were denied on March 18, 2004. On June 7, 2005, the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. affirmed the Opinion and Order of the District Court issued in Endo s favor on January 5, 2004. This affirmance by the Federal Circuit Court dismissed the claims that Endo s oxycodone extended release tablets infringe Purdue patents, and permanently enjoined Purdue from enforcing these patents.

On June 21, 2005, Purdue filed a petition with the Federal Circuit Court of Appeals seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 18, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue s petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. On February 1, 2006, we announced that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. We intend to continue marketing our generic oxycodone extended-release tablets at this time. In the event there is a final nonappealable judgment that Purdue s patents are valid and enforceable, we could face substantial liability for patent infringement and be obligated to pay Purdue damages in an amount to be determined by the District Court. Although there can be no assurance, we believe that we would be able to fund the payment of these damages without materially adversely affecting our business operations, including our acquisition and licensing strategy. See Item 3. Legal Proceedings for further information. We can make no prediction as to how or when the District Court will rule on remand or whether Purdue will appeal again in

the event we are successful on remand. Because we commenced commercial sale of our bioequivalent versions of OxyContin®, we could face substantial damages for patent infringement and be forced to stop selling our generic OxyContin® product if the District Court or Federal Circuit reverses their decisions in our favor and one or more of the Purdue patents is found valid and enforceable and there is a final court decision adverse to us.

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Most of our core products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to new regulation, including the development and implementation of Risk Minimization Action Plans (Risk MAP), which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.

Most of our core products contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. Specifically, in the past two years, reportedly widespread misuse or abuse of OxyContin®, a Purdue product containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. In addition, Purdue, the manufacturer of OxyContin®, faces numerous lawsuits, including class action lawsuits, related to OxyContin® misuse or abuse. On June 7, 2005, we began commercial sale of our oxycodone extended release tablets, 10mg, 20mg, 40mg and 80mg strengths, each bioequivalent versions of OxyContin®. We may be subject to litigation similar to the OxyContin® suits related to our generic version of OxyContin® or any other narcotic containing product we market.

The FDA or the DEA may impose new regulations concerning the manufacture and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of Risk MAPs, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such new regulations may be difficult and expensive for us to comply with, may delay our introduction of new products, may adversely affect our net sales and may have a material adverse effect on our business, profitability and cash flows. See The DEA limits the availability of the active ingredients used in our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

On July 13, 2005, the FDA asked Purdue to withdraw its product Palladone (hydromorphone hydrochloride extended release capsules) from the market after acquiring new information that serious and potentially fatal adverse reactions can occur when the product is taken together with alcohol. The data were gathered from a Purdue sponsored study testing the potential effects of alcohol use and showed that when Palladone is taken with alcohol the extended release mechanism is harmed, which can lead to dose-dumping. Dose-dumping is a term that describes the rapid release of the active ingredient from an extended release product into the blood stream, resulting in serious, even fatal, adverse events in some patients. Although we do not currently market any product comprised of a formulation similar to Purdue s Palladone, we cannot predict what, if any, new regulations may result from the FDA s actions with regard to Palladone and what effect such regulations would have on our business.

The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business.

The federal, state and local governmental authorities in the United States, the principal one of which applies to our products is the FDA, impose substantial requirements on the development, manufacture, labeling, sale, distribution, marketing, advertising, promotion and introduction of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. The submission of an NDA or ANDA to the FDA alone does not guarantee that the FDA will grant approval to market the product. Satisfaction of FDA requirements typically takes a number of years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product and is subject to uncertainty. The NDA approval process for a new product varies in time, generally requiring a minimum of 10 months, but could also take several years from the date of application. The timing for the ANDA approval process for generic products is difficult to estimate and can vary significantly.

NDA approvals, if granted, may not include all uses for which a company may seek to market a product. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses. Failure to comply with applicable regulatory requirements in this regard can result in, among other things, suspensions of approvals, seizures or recalls of products, injunctions against a product s manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions. Furthermore, changes in existing regulations or the adoption of new

regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. The effect of government regulation may be to delay marketing of our new products for a considerable period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete against us.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, including oxymorphone extended release (ER) or oxymorphone immediate release (IR), on a timely basis, if at all, or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

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In particular, on October 20, 2003, we announced that the FDA had issued approvable letters for both oxymorphone ER and oxymorphone IR. In the letters, the FDA requested that Endo address certain questions and provide additional clarification and information, including some form of clinical trials to further confirm the safety and efficacy of these products. We have undertaken additional clinical trials of both oxymorphone ER and oxymorphone IR to provide the FDA with additional safety and efficacy data.

On August 22, 2005, we reported the results from one of these Phase III clinical trails. In this multi center, randomized, double blind, parallel group trial, the safety and efficacy of oxymorphone ER were compared with placebo in 205 opioid naïve patients with moderate-to-serve chronic low back pain. This study demonstrated a statistically significant ($p<0.0001$) difference in pain scores between oxymorphone ER and placebo during a 12-week treatment period. On October 3, 2005, we reported the results from the second of these two Phase III clinical trials. In this multi-center, randomized, double-blind parallel group trial, the safety and efficacy of oxymorphone ER were again compared with placebo but this time in 142 opioid-experienced patients with moderate-to-severe chronic low back pain. This study demonstrated a statistically significant ($p<0.0001$) difference in pain scores from placebo during a 12-week treatment period. On October 3, 2005, we also announced positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. On the primary outcome variable (time to discontinuations for all causes over a 48-hour period), oxymorphone IR 20 mg and 10 mg, given every four to six hours, were both superior to placebo ($p<0.002$ and ($p<0.006$, respectively). In addition, in order to anticipate questions from the FDA with respect to the potential dose-dumping effect of opioids given the FDA s experience with Palladone (see Most of our core products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to new regulation, including the development and implementation of Risk MAPs, which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.), we have completed recently both in vitro and human testing of the effect of alcohol on any product oxymorphone ER. In the in vitro testing of alcohol and oxymorphone ER we did not find any effect on the time release mechanism of the product. With respect to the human testing of alcohol and oxymorphone ER, we do not believe that there was evidence of dose-dumping or signs of degradation of the controlled-release mechanism. We did note in this human testing a transient effect on blood levels which we believe reflects a short-lived increase in the absorption rate of oxymorphone already released from the tablet.

However, there is no certainty that the FDA will accept any of the above studies or what, if any, additional information the FDA will require for final approval of oxymorphone ER and oxymorphone IR. The FDA has not provided clear guidance as to whether or what type of in vitro and/or human testing of new extended-release opioid formulations may be required to determine whether dose-dumping occurs when a product is taken together with alcohol, nor has the FDA indicated what action they might take based on any results arising from this testing. There can be no assurance that the FDA will approve oxymorphone ER and oxymorphone IR or if the FDA will require significant additional testing which could result in a substantial delay in launching these products, if at all. If such testing is conducted, we cannot predict what actions, if any, the FDA may take based on the results of such testing. Any delay in obtaining, or failure to obtain, FDA approval of oxymorphone ER or IR would delay our ability to bring these products to market and would adversely affect our ability to generate revenue from these products. If the FDA approves oxymorphone ER and IR, we cannot assure that it may not take other actions, such as requiring certain labeling or restricting the marketing of one or both of these products, either of which may also adversely affect our ability to generate revenue from these products.

The current FDA standards of approving new pharmaceutical products are more stringent than those that were applied in the past. These standards were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has recently expressed an intention to develop such databases for certain of these products, including many opioids.

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics and laboratory tests may indicate the potential for having mutagenic effects. More stringent controls of the levels of these impurities have been required and may continue to be required for FDA approval of products containing these impurities, such as oxymorphone. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary for new or existing products containing such impurities. The FDA s more stringent requirements together with any additional testing or remedial measures that may be necessary could result in increased costs for, or delays in, obtaining approval for certain of our products in development. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless such mutagenic effects are believed to indicate a significant risk to patient health, we cannot make any such assurance.

The FDA and the DEA have important and complementary responsibilities with respect to our business. The FDA administers an application process to assure that marketed products are safe, effective and consistently of uniform, high quality. The DEA administers registration, drug allotment and accountability systems to assure against loss and diversion of controlled substances. Both

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agencies have trained investigators that routinely, or for cause, conduct inspections, and both have authority to enforce their statutory authority and regulations using administrative remedies as well as civil and criminal sanctions.

The FDA regulates the facilities and procedures used to manufacture pharmaceutical products in the United States or for sale in the United States. Such facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with current good manufacturing practices, or cGMP, regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects our third party manufacturing facilities and procedures to assure compliance. The FDA may cause a recall or withdrawal of product approvals if regulatory standards are not maintained. The FDA approval to manufacture a drug is site-specific. In the event an approved manufacturing facility for a particular drug is required by the FDA to cease or curtail operations, or otherwise becomes inoperable, or the manufacturing contract applicable thereto terminates, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business, profitability and cash flows.

The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could result in imposition of civil penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances. See also The DEA limits the availability of the active ingredients used in our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. Changes could, among other things, require expanded or different labeling, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations. In December 2003, Congress enacted new requirements for testing drug products in children, which may increase the time and cost necessary for new drug development. Congress recently passed measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Among other things, these measures are intended to limit regulatory delays of generic drug applications and penalize companies that reach certain types of agreements with makers of brand name drugs to delay the introduction of generic versions. These changes could result in increased generic competition for our branded and generic products and could have a material adverse effect on our business, financial condition and results of operations. The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as the FDA s approval of products are uncertain.

Before obtaining regulatory approvals for the sale of any of our products, other than generic products, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals.

The rate of patient enrollment sometimes delays completion of clinical studies. There is substantial competition to enroll patients in clinical trials for pain management products, and such competition has delayed clinical development of our products in the past. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements that may also delay clinical trials. We cannot assure you that we will not

experience delays or undesired results in these or any other of our clinical trials.

We presently have two products under NDA review, three products in Phase III of clinical trials and four products in Phase II of clinical trials. We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, including oxymorphone ER or oxymorphone IR, on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue, as well as adversely affect the price of our common stock.

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In particular, on October 20, 2003, we announced that the FDA had issued approvable letters for both oxymorphone ER and oxymorphone IR. In the letters, the FDA requested that Endo address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of these products. We have undertaken additional clinical trials of both oxymorphone ER and oxymorphone IR to provide the FDA with additional safety and efficacy data. On August 22, 2005, we reported the results from one of these Phase III clinical trials. In this multi center, randomized, double blind, parallel group trial, the safety and efficacy of oxymorphone ER were compared with placebo in 205 opioid naïve patients with moderate-to-severe chronic low back pain. This study demonstrated statistically significant ($p<0.0001$) difference in pain scores between oxymorphone ER and placebo during a 12-week treatment period. On October 3, 2005, we reported the results from the second of these two Phase III clinical trials. In this multi-center, randomized, double-blind, parallel group trial, the safety and efficacy of oxymorphone ER were again compared with placebo but this time in 142 opioid-experienced patients with moderate-to-severe chronic low back pain. This study demonstrated a statistically significant ($p<0.0001$) difference in pain scores from placebo during a 12-week treatment period. On October 3, 2005, we also announced positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. On the primary outcome variable (time to discontinuations for all causes over a 48-hour period), oxymorphone IR 20 mg and 10 mg, given every four to six hours, were both superior to placebo ($p<0.002$ and $p<0.006$, respectively). We submitted complete responses to the approvable letters to the FDA on December 22, 2005. Under the PDUFA guidelines, the FDA has confirmed our six-month PDUFA date as June 22, 2006, which is the date on which we expect to receive action letters from the FDA on these filings. There is no certainty that the FDA will accept these results or what, if any, additional information the FDA will require for final approval of oxymorphone ER and oxymorphone IR. There can be no assurance that the FDA will approve oxymorphone ER and oxymorphone IR or if the FDA will require significant additional testing which could result in a substantial delay in launching these products, if at all.

Before obtaining regulatory approvals for certain generic products, we must conduct limited clinical or other trials to show comparability to the branded products. A failure to obtain satisfactory results in these trials would prevent us from obtaining required regulatory approvals.

The success of our acquisition and licensing strategy is subject to uncertainty and any completed acquisitions or licenses may reduce our earnings, be difficult to integrate, not perform as expected or require us to obtain additional financing.

We regularly evaluate selective acquisitions and look to continue to enrich our product line by acquiring rights to additional products and compounds. Such acquisitions may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. However, we cannot assure you that we will be able to complete acquisitions that meet our target criteria on satisfactory terms, if at all. In particular, we may not be able to identify suitable acquisition candidates, and we may have to compete for acquisition candidates. Our competitors may have greater resources than us and therefore be better able to complete acquisitions or may cause the ultimate price we pay for acquisitions to increase. If we fail to achieve our acquisition goals, our growth may be limited.

Acquisitions may expose us to additional risks and may have a material adverse effect on our profitability and cash flows. Any acquisitions we make may:

- fail to accomplish our strategic objectives;
- not be successfully combined with our operations;
- not perform as expected; and
- expose us to cross border risks.

In addition, based on current acquisition prices in the pharmaceutical industry, acquisitions could decrease our income per share and add significant intangible assets and related amortization charges. Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in leverage, or increased debt obligations as compared to equity, and dilution of ownership. We may not be able to finance acquisitions on terms satisfactory to us.

Further, if we are unable to maintain, on commercially reasonable terms, product, compound or other licenses that we have acquired, our ability to develop or commercially exploit our products may be inhibited.

Our growth and development will depend on developing, commercializing and marketing new products, including both our own products and those developed with our collaboration partners. If we do not do so successfully, our growth and development will be impaired.

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully commercialize new branded and generic pharmaceutical products in a timely manner. As a result, we must continually develop, test and manufacture new

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products, and these new products must meet regulatory standards and receive requisite regulatory approvals. Products we are currently developing may or may not receive the regulatory approvals necessary for us to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, can be successfully commercialized. Some of our collaboration partners may decide to make substantial changes to a product s formulation or design, may experience financial difficulties or have limited financial resources, any of which may delay the development, commercialization and/or marketing of new products. In addition, if a co-developer on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and, possibly, additional costs in developing and marketing that product.

We conduct research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. Typically, research expenses related to the development of innovative compounds and the filing of NDAs for these products are significantly greater than those expenses associated with ANDAs for generic products. As we continue to develop new products, our research expenses will likely increase. Because of the inherent risk associated with research and development efforts in our industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA approved new pharmaceutical products. Also, after we submit an NDA or ANDA, the FDA may request that we conduct additional studies and as a result, we may be unable to reasonably predict the total research and development costs to develop a particular product.

Our ability to protect our proprietary technology, which is vital to our business, is uncertain.

Our success, competitive position and amount of future income will depend in part on our ability to obtain patent protection relating to the technologies, processes and products we are currently developing and that we may develop in the future. Our policy is to seek patent protection and enforce the intellectual property rights we own and license. We cannot assure you that patent applications we submit and have submitted will result in patents being issued. If an advance is made that qualifies as a joint invention, the joint inventor or his or her employer may have rights in the invention. We cannot assure you that a third party will not infringe upon, design around or develop uses not covered by any patent issued or licensed to us or that these patents will otherwise be commercially viable. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the U.S. Patent and Trademark Office, or PTO, or in legal proceedings. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the United States than abroad. Foreign patents may be more difficult to protect and/or the remedies available may be less extensive than in the United States. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical field. This may limit our ability to obtain or utilize those patents internationally. Patent applications in the United States are maintained in secrecy until at least 18 months after the filing of the application with the PTO and, since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries, we cannot be certain that we were the first creator of the inventions covered by pending patent applications or the first to file patent applications on those inventions. Several drug companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Others may file patent applications and may receive patents that may conflict with patents or patent applications we have obtained or licensed for our use, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. We cannot assure you that any of our pending patent applications will be allowed, or, if allowed, whether the scope of the claims allowed will be sufficient to protect our products. Litigation to establish the validity of patents, to defend against patent infringement claims of others and to assert patent infringement claims against others can be expensive and time-consuming even if the outcome is favorable to us. If the outcome is unfavorable to us, this could have a material adverse effect on our business. We have taken and may, in the future, take steps to enhance our patent protection, but we cannot assure you that these steps will be successful or that, if unsuccessful, our patent protection will be adequate.

We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We attempt to protect our proprietary technology in large part by confidentiality agreements with our employees, consultants and other contractors. We cannot assure you, however, that these agreements will not be breached, that we would have adequate remedies for any breach or that competitors will not know of, or independently discover, our trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our products or know-how or require licensing and the payment of significant fees or royalties by us in order to produce our products. Moreover, we cannot

assure you that our technology does not infringe upon any valid claims of patents that other parties own.

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In the future, if we were found to be infringing on a patent, we might have to seek a license to use the patented technology. We cannot assure you that, if required, we would be able to obtain such a license on terms acceptable to us, if at all. If a third party brought a legal action against us or our licensors, we could incur substantial costs in defending ourselves, and we cannot assure you that such an action would be resolved in our favor. If such a dispute were to be resolved against us, we could be subject to significant damages, and the testing, manufacture or sale of one or more of our technologies or proposed products, if developed, could be enjoined.

We cannot assure you as to the degree of protection any patents will afford, whether the PTO will issue patents or whether we will be able to avoid violating or infringing upon patents issued to others or that others will not manufacture and distribute our patented products upon expiration of the applicable patents. Despite the use of confidentiality agreements and non-compete agreements, which themselves may be of limited effectiveness, it may be difficult for us to protect our trade secrets.

If the efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory means to limit the use of generics and certain other products are successful, our sales may suffer.

Pharmaceutical companies that produce patented brand products are increasingly employing a range of legal and regulatory strategies to delay the introduction of competing generics and certain other products to which we do not have a right of reference to all necessary preclinical and clinical data. Opposing such measures can be costly and time-consuming and result in delays in the introduction of our products.

The products for which we are developing generic versions may be claimed by their manufacturer to be protected by one or more patents. If we file an ANDA to seek FDA approval of our generic version of such a drug, we are required to certify that any patent or patents listed as covering the approved listed drug are invalid, unenforceable or will not be infringed by our generic version. Similar certification and notification requirements apply to new drug applications filed under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, where we rely on information to which we do not have a right of reference. Once the FDA accepts our ANDA or section 505(b)(2) NDA filing, we are required to notify the brand manufacturer of this fact. The brand manufacturer then has 45 days from the receipt of the notice in which to sue us for patent infringement. If it does so, the FDA is generally prevented from granting approval of the ANDA or section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in our favor or expiration of the patent(s).

One of the key motivators for challenging patents is the 180-day market exclusivity period vis a vis other ANDA applicants granted to the developer of a generic version of a product that is the first to have its ANDA accepted for filing by the FDA and whose filing includes a certification that the applicable patent(s) are invalid, unenforceable and/or not infringed (a Paragraph IV certification) and that prevails in litigation with the manufacturer of the branded product over the applicable patent(s). Given the recent passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the 2003 Medicare Act, with accompanying amendments to the Hatch Waxman Act, this marketing exclusivity would begin to run upon the earlier of our commercial launch of the generic product or upon an appellate court decision in our favor. However, we cannot assure you that we will be prepared, authorized or willing (depending on the circumstances) to commercialize the applicable product prior to an appellate decision in our favor.

We had received favorable decisions from the U.S. District Court for the Southern District of New York and the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. in our patent litigation with respect to our extended release oxycodone product. This litigation was instituted by Purdue, the manufacturer of the brand OxyContin®, and resulted in a delay in our ability to obtain final FDA approval for our extended release oxycodone product. On June 7, 2005, the Court of Appeals affirmed the Opinion and Order of the District Court in our favor. On the same day, we launched the 10mg, 20mg, 40mg and 80mg strengths of our bioequivalent versions of OxyContin®.

On June 21, 2005, Purdue filed a petition with the Federal Circuit Court of Appeals seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 18, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue s petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. On February 1, 2006, we announced that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. We intend to continue marketing our generic oxycodone extended-release tablets at this time. In the event there is a final nonappealable judgment that Purdue s patents are valid and enforceable, we could face substantial liability for patent infringement and be obligated to pay Purdue damages in an amount to be determined by the District Court. Although there can be no

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assurance, we believe that we would be able to fund the payment of these damages without materially adversely affecting our business operations, including our acquisition and licensing strategy. See Item 3. Legal Proceedings for further information. We can make no prediction as to how or when the District Court will rule on remand or whether Purdue will appeal again in the event we are successful on remand. Because we commenced commercial sale of our bioequivalent versions of OxyContin®, we could face substantial damages for patent infringement and be forced to stop selling our generic OxyContin® product if the District Court or Federal Circuit reverses their decisions in our favor and one or more of the Purdue patents is found valid and enforceable and there is a final court decision adverse to us.

We may be the subject of product liability claims or product recalls, and we may be unable to obtain or maintain insurance adequate to cover potential liabilities.

Our business exposes us to potential liability risks that arise from the testing, manufacturing, marketing and sale of our products. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse publicity as a result of product liability claims. Product liability is a significant commercial risk for us. Some plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue.

We cannot assure you that a product liability claim or series of claims brought against us would not have an adverse effect on our business, financial condition, profitability and cash flows. If any claim is brought against us, regardless of the success or failure of the claim, we cannot assure you that we will be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities or the cost of a recall.

The availability of third party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third party reimbursement is not adequately provided.

Our ability to commercialize our products depends, in part, on the extent to which reimbursement for the costs of these products is available from government health care programs, private health insurers and others. We cannot assure you that third party insurance coverage will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government, private insurers and other third party payers are increasingly attempting to contain health care costs by (1) limiting both coverage and the level of reimbursement (including adjusting co-pays) for products approved for marketing by the FDA, (2) refusing, in some cases, to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval and (3) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products.

On December 8, 2003, President Bush signed into law the Medicare Modernization Act of 2003. The Medicare Modernization Act created a new prescription drug coverage program for people with Medicare through a new system of private market insurance providers; the program began in January 2006. This new benefit may result in an increased use of formularies (listings of prescription drugs approved for use) such that, in the event a Medicare beneficiary s medications are not listed on the applicable formulary, such Medicare beneficiary may not receive reimbursement for such medications. Moreover, once these formularies are established, Medicare will not be obligated to pay for drugs omitted from a formulary, and the cost of these non-covered drugs will not be counted towards the $3,600 annual out-of-pocket beneficiary deductible established by the Medicare Modernization Act. Further, beginning in 2006, Medicare prescription drug program beneficiaries are not permitted to purchase private insurance policies, known as Medigap policies, to cover the cost of off-formulary medications. If our products are excluded from these new formularies, demand for our products might decrease and we may be forced to lower prices for our products, which may adversely affect our business and our results of operations. If government and third party payers do not provide adequate coverage and reimbursement levels for users of our products, the market acceptance of these products could be adversely affected. In addition, the following

factors could significantly influence the purchase of pharmaceutical products, which would result in lower prices and a reduced demand for our products that might force us to reduce the price of these products to remain competitive:

- the trend toward managed health care in the United States;
- the growth of organizations such as HMOs and managed care organizations;
- legislative proposals to reform health care and government insurance programs; and
- price controls and non-reimbursement of new and highly priced medicines for which the economic therapeutic rationales are not established.

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Our reporting and payment obligations under the Medicaid rebate program and other governmental pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration in return for the purchase of our products. Sanctions for violating these laws include criminal penalties and civil sanctions and possible exclusion from the Medicare, Medicaid, and other government health care programs. There can be no assurance that our practices will not be challenged under these laws in the future or that such a challenge would not have a material adverse effect on our business or results of operations.

We also are subject to federal and state laws prohibiting the presentation (or the causing to be presented) of claims for payment (by Medicare, Medicaid, or other third-party payers) that are determined to be false, fraudulent, or for an item or service that was not provided as claimed. These false claims statutes include the Federal civil and criminal False Claims Acts, which allow any person to bring suit in the name of the government alleging false or fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in the health care industry in recent years. These actions against health care companies may result in payment of fines or exclusion from the Medicare, Medicaid, and/or other government health care programs as the result of an investigation arising out of the action.

We and other pharmaceutical companies are defendants in a number of lawsuits filed by local and state government entities, alleging generally that we and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. Endo intends to defend these lawsuits vigorously. Depending on developments in the litigation however, as with all litigation, there is a possibility that the company will suffer adverse decisions or verdicts of substantial amounts, or that the company will enter into monetary settlements in one or more of these actions. Government regulations regarding reporting and payment obligations are complex and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to the pertinent government agency (or agencies), or to the amounts themselves. In addition, because our processes for these calculations and our judgments supporting these calculations involve, and will continue to involve, subjective decisions, these calculations are subject to the risk of errors. As noted above, any governmental agency that commences an investigation of us could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments and even in the absence of such ambiguity a governmental authority may take a position contrary to a position we have taken, and may impose civil and/or criminal sanctions. Any such penalties or sanctions could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Once approved, there is no guarantee that the market will accept our future products, and regulatory requirements could limit the commercial usage of our products.

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. We cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline. In addition, many of our products contain narcotic ingredients that carry stringent record keeping obligations, strict storage requirements and other limitations on these products

availability, which could limit the commercial usage of these products.

We sell our products to a limited number of wholesale drug distributors and large pharmacy chains, the loss of whose business could materially affect our sales.

We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply our products to pharmacies, hospitals, governmental agencies and physicians. Three distributors and one pharmacy chain individually accounted for 31%, 27%, 13% and 3% respectively, of net sales in 2005, 29%, 18%, 18% and 9% respectively, of net sales in 2004, and 26%, 26%, 19% and 11% respectively, of net sales in 2003. If we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our net sales, profitability and cash flows could be materially and adversely affected.

We are dependent on outside manufacturers for the manufacture of our products; therefore, we will have limited control of the manufacturing process and related costs. Certain of our manufacturers currently constitute the sole source of one or more of our products.

Third party manufacturers currently manufacture all of our products pursuant to contractual arrangements. Certain of our manufacturers currently constitute the sole source of one or more of our products. Because of contractual restraints and the lead-time necessary to obtain FDA approval, and possibly DEA registration, of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers.

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Because all of our products are manufactured by third parties, we have a limited ability to control the manufacturing process or costs related to this process. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing which would have a material adverse impact on our business, profitability and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency, or EPA, and the Occupational Safety and Health Administration, or OSHA, and their counterpart agencies at the state level, could slow down or curtail operations of third party manufacturers.

We have entered into minimum purchase requirement contracts with some of our third party manufacturers. In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., pursuant to which Novartis has agreed to manufacture certain of our commercial products in addition to products in development. As of December 31, 2005, we are required to purchase a minimum of $7.8 million per year through December 31, 2009 from Novartis. We also have a long-term contract with Teikoku Seiyaku Co., Ltd. under which Teikoku manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We are required to purchase a minimum of $18 million of Lidoderm® at cost of goods from Teikoku in 2006. In addition, we may consider entering into additional manufacturing arrangements with third party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals and taking the other steps necessary to begin commercial production by these manufacturers. If the market for the products manufactured by these third parties substantially contracts or disappears, we will continue to be financially obligated under these contracts, an obligation which could have a material adverse effect on our business.

We are dependent on third parties to supply all raw materials used in our products and to provide services for certain core aspects of our business. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, profitability and cash flows.

We rely on third parties to supply all raw materials used in our products. In addition, we rely on third party suppliers, distributors and collaboration partners to provide services for certain core aspects of our business, including manufacturing, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. All third party suppliers and contractors are subject to FDA, and very often DEA, requirements. Our business and financial viability are dependent on the regulatory compliance of these third parties, and on the strength, validity and terms of our various contracts with these third party manufacturers, distributors and collaboration partners. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, financial condition, profitability and cash flows.

In addition, we have entered into minimum purchase requirement contracts with some of our third party suppliers. If the market for the products that utilize these raw materials substantially contracts or disappears, we will continue to be financially obligated under these contracts and meeting such obligations could have a material adverse effect on our business.

The DEA limits the availability of the active ingredients used in our current products and products in development and, as a result, our procurement quota may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine, fentanyl, sufentanil and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high

degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Furthermore, the DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Any delay or refusal by the DEA in establishing our procurement quota for controlled substances could delay or stop our clinical trials, product launches or could cause trade inventory disruptions for those products that have already been launched, which could have a material adverse effect on our business, financial position and results of operations.

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Sales of our products may be adversely affected by the consolidation of the wholesale drug distribution and retail pharmacy industries, a trend which may continue.

The network through which we sell our products has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. We expect that consolidation of drug wholesalers and retailers will place competitive pressures on drug manufacturers, including us. If we lose any of these customer accounts, or if our relationship with them were to deteriorate, our business could also be materially and adversely affected. Orders for our products may increase or decrease depending on the inventory levels held by our major customers. Significant increases and decreases in orders from our major customers could cause our operating results to vary significantly from quarter to quarter.

Retail availability of our products is greatly affected by the inventory levels our customers hold. We monitor wholesaler inventory of our products using a combination of methods, including tracking prescriptions filled at the pharmacy level to determine inventory amounts the wholesalers have sold to their customers. Beginning in 2005, pursuant to our agreement with one of our significant wholesale customers, we receive inventory level reports. For other wholesalers where we do not receive inventory level reports, however, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive inventory production, inadequate supplies of products in distribution channels, insufficient or excess product available at the retail level, and unexpected increases or decreases in orders from our major customers. Forward buying by wholesalers, for example, may result in significant and unexpected changes in customer orders from quarter to quarter. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or projections. If our financial results are below expectations for a particular period, the market price of our securities may drop significantly.

We may not be able to maintain our current insurance policies covering our business, assets, directors and officers and product liability claims and we may not be able to obtain new policies in the future.

Property, product liability, directors and officers and general liability insurance represent significant costs to us. Since the events of September 11, 2001, and due to recent concerns over corporate governance in the U.S., corporate accounting scandals and product liability lawsuits related to pharmaceuticals, liability and other types of insurance have become more difficult and costly to obtain. Unanticipated additional insurance costs could have a material adverse effect on our results of operations and cash flows. There can be no assurance that we will be able to maintain our existing insurance policies or obtain new policies in meaningful amounts or at a reasonable cost. Any failure to obtain or maintain any necessary insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to retain our key personnel, and continue to attract additional professional staff, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific and technical personnel. The loss of key scientific and technical personnel or the failure to recruit additional key scientific and technical personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions and have employment agreements with our key executives, we cannot assure you that we will succeed in retaining this personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

We have significant goodwill and other intangible assets. Consequently, potential impairment of goodwill and other intangibles may significantly impact our profitability.

Goodwill and other intangibles represent a significant portion of our assets and stockholders equity. As of December 31, 2005, goodwill and other intangibles comprised approximately 20% of our total assets and 33% of our stockholders equity. Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit s fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit s goodwill is less than its carrying amount. Our other intangible assets, consisting of licenses and patents, are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The

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impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of goodwill and other intangible assets, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill or other intangible assets occur.

Our credit agreement limits our ability to conduct our business, which could negatively affect our ability to finance future capital needs and engage in other business activities.

The covenants in our existing credit agreement contain a number of significant limitations on our ability to, among other things:

pay dividends;

incur additional indebtedness;

create liens on our assets; and

acquire or dispose of assets.

These restrictive covenants could negatively affect our ability to finance our future capital needs, engage in other business activities or withstand a future downturn in our business or the economy.

Under our credit agreement, we are required to maintain certain specified financial ratios and meet financial tests, including maintaining a specific level of EBITDA, as defined therein. Our ability to comply with these may be affected by matters beyond our control. A breach of any of these covenants would prevent us from being able to draw under our revolving loan and will result in a default under our credit agreement.

We are a holding company with no operations.

We are a holding company with no direct operations. Our principal assets are the equity interests we hold in our operating subsidiaries. As a result, we are dependent on loans, dividends and other payments from our subsidiaries to generate the funds necessary to meet our financial obligations. Our subsidiaries are legally distinct from us and have no obligation to make funds available to us.

Our revenues and operating results may fluctuate in future periods and we may fail to meet expectations, which may cause the price of our common stock to decline.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. Accordingly, one cannot predict our quarterly financial results based on our full-year financial guidance. We cannot predict with certainty the timing or level of sales of our products in the future. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Our operating results may fluctuate due to various factors including those set forth above. As a result of these factors, we believe that period-to-period comparisons of our operating results are not a good indication of our future performance. For example, our 2006 guidance is based upon our assumptions that our sales of Lidoderm®, Depodur® and Frova® will grow over the course of the year and that we will launch Synera™ in the second half of 2006.

We could be influenced by a significant shareholder whose interests may not be aligned with the interests of our other shareholders.

Endo Pharma LLC at one time owned a majority of the shares of our common stock and currently owns approximately 8.0% of the shares of our common stock. Endo Pharma LLC is, in turn, controlled by affiliates of Kelso & Company, which currently own 83.6% of Endo Pharma LLC. Two of our directors, Mr. Goldberg and Mr. Wahrhaftig, are Managing Directors of Kelso. Three of our directors, Mr. Goldberg, Mr. Wahrhaftig and Ms. Ammon, serve as members of the Board of Managers of Endo Pharma LLC. These individuals therefore direct how Endo Pharma LLC votes its shares on corporate matters.

As a result, Endo Pharma LLC and Kelso may be able to significantly influence the outcome of stockholder votes, including votes concerning the election of the majority of directors, the adoption or amendment of provisions in our charter or by-laws, the approval of mergers, decisions affecting our capital structure and other significant corporate transactions. Kelso may also have significant influence over our management and policies. The interests of Endo Pharma LLC and Kelso may conflict with your

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interests. Their influence may also have the effect of deterring hostile takeovers, delaying or preventing changes in control or changes in management or limiting the ability of our stockholders to approve transactions that they may deem to be in their best interests.

The composition of our board of directors will change in the near-term.

We have been advised by Brian T. Clingen and Michael W. Mitchell that they each intend to resign from our board of directors effective March 15, 2006, in order to devote more time to their respective current activities. In addition, Michael B. Goldberg and David I. Wahrhaftig, both managing directors of Kelso, have advised us that they also intend to resign from our board of directors on the same date; these resignations are consistent with Kelso s practice of not having its partners serve on the boards of directors of public companies unless Kelso s level of beneficial stock ownership in the company is significant and warrants such participation. Following such resignations, our board of directors will have seven board members, including John J. Delucca who was appointed on January 6, 2006 to replace Endo board member Frank J. Loverro, a managing director of Kelso, who resigned as a board member on that date. In order to ease this transition, we have underway an active process to identify persons qualified to serve as members of our board of directors and may propose such persons for election or appointment in the future.

Our stock price may be volatile, and your investment in our common stock could decline in value.

The market prices for securities of healthcare companies in general have been highly volatile and may continue to be highly volatile in the future. Within the last 12 months through December 31, 2005, our stock has traded between $19.02 and $31.93 per share. The following factors, in addition to other risk factors described in this section, may cause the market price of our common stock to change:

- FDA approval or disapproval of any of the drug applications we have submitted;
- the success or failure of our clinical trials;
- competitors announcing technological innovations or new commercial products;
- introduction of generic substitutes for our products, including the filing of ANDAs with respect to generic versions of our branded products, including Lidoderm®;
- developments concerning our or others proprietary rights, including patents;
- competitors publicity regarding actual or potential products under development;
- regulatory developments in the United States and foreign countries, or announcements relating to these matters;
- period-to-period fluctuations in our financial results;

new legislation in the United States relating to the sale or pricing of pharmaceuticals;

litigation; and

economic and other external factors, including disasters and other crises.

If our stockholders sell substantial amounts of our common stock, the market price of our common stock may fall.

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options, the market price of our common stock may fall. These sales also may make it more difficult for us to sell equity or equity related securities in the future at a time and price that we deem appropriate.

At March 1, 2006, approximately 12.6 million shares of common stock, representing approximately 9.5% of our common stock currently outstanding, were eligible for sale, subject to compliance with Rule 144 or Rule 145(d) under the Securities Act.

Of the 3,229,430 shares that may be issued upon the exercise of options outstanding as of December 31, 2005, 1,430,058 are vested, currently exercisable and eligible for sale. The sale of these shares is unrestricted, subject to any lock-up agreements that may be entered into with underwriters in connection with any underwritten offering of such shares covered by this prospectus.

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We have not paid, and may not pay, dividends and therefore, unless our stock appreciates in value, investors in our stock may not benefit from holding our stock.

We have not paid any cash dividends since our inception. Furthermore, our existing credit facility limits our ability to pay dividends. We may not pay cash dividends in the future. As a result, investors in our stock will not be able to benefit from owning our stock unless the shares that these investors acquire appreciate in value.

Item 1B ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

We lease all of our properties pursuant to operating leases. Of these, the most significant are our research and development facility located in Westbury, New York and our corporate headquarters in Chadds Ford, Pennsylvania. A description of the material terms of each of the agreements pertaining to these properties follows:

Chadds Ford, Pennsylvania

Painters Crossing One Associates, L.P. Lease Agreement. On May 5, 2000, we entered into a ten-year lease with Painters Crossing One Associates, L.P. pursuant to which Painters Crossing leases to us a building comprised of approximately 47,756 square feet located in Chadds Ford, Pennsylvania. By amendment dated February 26, 2001, this lease commenced on August 1, 2001 and will end on August 31, 2010. However, we, at our discretion, have the right to terminate this lease at the end of the fifth year, by providing two years notice and paying a fixed termination fee to Painters Crossing. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

Painters Crossing Two Associates, L.P. Lease Agreement. On November 13, 2003, we entered into a ten-year lease with Painters Crossing Two Associates, L.P. pursuant to which Painters Crossing will lease to us a building comprised of approximately 64,424 square feet located across the street from our corporate headquarters in Chadds Ford, Pennsylvania. By amendment dated February 16, 2005, this lease commenced on February 1, 2005 and will end on January 31, 2015. We, at our discretion, have the right to terminate this lease at the end of the sixth year, by providing two years notice and paying a fixed termination fee to Painters Crossing. During the term of the lease, the annual rent is a fixed amount paid in equal monthly installments that increase after the first five years of the lease.

Westbury, New York

Dawson Holding Company. Under this agreement, dated January 6, 2003, we lease a 24,190 square foot facility in Westbury, New York. The annual rent due for this facility is $152,397 in the first year of the lease, escalating by 4% each year thereafter. This ten-year lease is not assignable without the consent of the landlord, Dawson Holding. This lease may by terminated (1) by us, at the end of the fifth year with the

payment to Dawson Holding of approximately $239,000 plus 75% of any additional rent owed during the fifth lease year, (2) by us, with 30 days notice, if the facility has suffered a fire or other casualty and Dawson Holding has not substantially restored it to its condition existing immediately prior to the fire or other casualty within one year from the date Dawson Holding received insurance proceeds, (3) by Dawson Holding, for our default under the lease, or (4) by either Dawson Holding or us, within 30 days of any condemnation.

Item 3. ***Legal Proceedings***

While we cannot predict the outcome of the following legal proceedings, we believe that the claims against us are without merit, and we intend to vigorously defend our position. An adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position and results of operations. No amounts have been accrued with respect to any of these unsettled legal proceedings at December 31, 2005.

Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 00 Civ. 8029 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 2109 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 8177 (SHS) (S.D.N.Y.)

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On October 20, 2000, The Purdue Frederick Company and related companies (Purdue Frederick) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc. (EPI), in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent version of Purdue Frederick s OxyContin® (oxycodone hydrochloride extended-release tablets), 40mg strength, infringes three of its patents. This suit arose after EPI provided the plaintiffs with notice that its ANDA submission for a bioequivalent version of Purdue Frederick s OxyContin®, 40mg strength, challenged the listed patents for OxyContin® 40mg tablets. On March 13, 2001, Purdue Frederick filed a second suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent versions of Purdue Frederick s OxyContin®, 10mg and 20mg strengths, infringe the same three patents. This suit arose from EPI having amended its earlier ANDA on February 9, 2001 to add bioequivalent versions of the 10mg and 20mg strengths of OxyContin®. On August 30, 2001, Purdue Frederick filed a third suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent version of Purdue Frederick s OxyContin®, 80mg strength, infringes the same three patents. This suit arose from EPI having amended its earlier ANDA on July 30, 2001 to add the bioequivalent version of the 80mg strength of OxyContin®.

For each of the 10mg, 20mg, 40mg and 80mg strengths of this product, EPI made the required Paragraph IV certification against the patents listed in the FDA s Orange Book as covering these strengths of OxyContin®. EPI pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI s formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI also counterclaimed for antitrust damages based on allegations that Purdue Frederick obtained the patents through fraud on the United States Patent and Trademark Office and is asserting them while aware of their invalidity and unenforceability.

The trial of the patent claims in all three of the suits against us and EPI concluded on June 23, 2003. On January 5, 2004, the District Court issued an opinion and order holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to inequitable conduct. The District Court, therefore, dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the District Court s infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo s favor by the U.S. District Court for the Southern District of New York on January 5, 2004. This affirmance by the Federal Circuit Court dismissed the claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoined Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue s petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005.

On February 1, 2006, the Federal Circuit granted Purdue s motion for panel rehearing, vacated the June 7, 2005 decision of the District Court, and remanded to the District Court for further proceedings. The Federal Circuit s decision on rehearing directs the District Court to give further consideration to its previous finding of unenforceability due to inequitable conduct. The Federal Circuit also affirmed the District Court s finding that Endo s oxycodone extended-release tablets infringe the Purdue patents. The parties have jointly requested that the district court conduct a status hearing to discuss proceedings on the remand.

The Company has reviewed the Federal Circuit Court s opinion with counsel and believes that, on remand, the District Court should again find that Purdue s patents are unenforceable due to Purdue s inequitable conduct before the U.S. Patent and Trademark Office. Endo does not currently intend to pursue an en banc rehearing of the Federal Circuit Court s opinion, but rather intends to pursue the remand proceedings in the District Court. In the event of a final, nonappealable adverse determination against it, the company would be required to terminate its sales of its bioequivalent version of OxyContin®. We can make no prediction as to how or when the District Court will rule on remand or whether Purdue will appeal again in the event we are successful on remand.

In the event that there is a final nonappealable judgment that Purdue s patents are valid and enforceable, Endo could face substantial liability for patent infringement and be obligated to pay Purdue damages in an amount to be determined by the District

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Court. Damages may be calculated based on profits that Purdue may have lost to Endo s sales of its generic OxyContin for the period the company sold the product, a reasonable royalty, and/or a variety of other legal theories, together with pre- or post-judgment interest on any such damages award. Although there can be no assurance, the company believes that it would be able to fund the payment of these damages without materially adversely affecting the operations of its business, including its acquisition and licensing strategy. The outcome of litigation is always uncertain, as are the imposition and level of damages. However, after consultation with counsel, the company believes that it is unlikely that Purdue would be awarded enhanced damages, such as treble damages.

On June 8, 2005, EPI filed a complaint against Purdue Pharma L.P., the Purdue Frederick Company, the Purdue Pharma Company, Ivax Corporation and Ivax Pharmaceuticals, Inc. (collectively, Defendants) in the Superior Court of the Judicial District of Norwalk-Stamford Connecticut, alleging a violation of the Connecticut Unfair Trade Practices Act. Specifically, EPI claimed that the Defendants have engaged in unfair trade practices by launching an authorized generic version of Purdue s OxyContin® on the heels of the Federal Circuit s ruling that Purdue obtained its patents on OxyContin® through inequitable conduct. EPI sought temporary and permanent injunctions enjoining Defendants from marketing or selling their authorized generic OxyContin® during Endo s 180-day market exclusivity period, as well as compensatory damages, punitive damages, and attorneys fees incurred in connection with the action. Defendants removed the case to the U.S. District Court for the District of Connecticut on July 1, 2005. In addition, Purdue filed a Motion to Dismiss, on July 1, 2005, and Ivax filed a Motion to Dismiss on July 8, 2005. EPI filed a Motion for Remand on August 5, 2005. On September 19, 2005, the District of Connecticut denied EPI s motion for remand. On the same date, EPI voluntarily dismissed the complaint without prejudice to refiling.

Litigation similar to that described above may also result from products we currently have in development, as well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

Linda Serafin, et al. v. Purdue Pharma L.P., et al., No. 103031/04 (Supreme Court of the State of New York, County of New York)

On February 27, 2004, EPI was named, along with three other pharmaceutical companies, a hospital, and a doctor, as a defendant in a lawsuit filed by Linda Serafin and Michael Serafin in the Supreme Court of the State of New York, County of New York. The complaint alleged that EPI and another defendant manufactured oxycodone, OxyContin® and/or Percocet®. The complaint alleged that the defendants failed to adequately warn about the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs sustained injury. Plaintiffs counsel agreed to dismiss EPI, along with the other pharmaceutical manufacturer companies, with prejudice. EPI was dismissed without any payment or other remuneration from the Company. The Stipulation of Dismissal with respect to EPI was filed on January 17, 2006.

Litigation similar to that described above may also be brought by other plaintiffs in other jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

Pricing Litigation

A number of cases, brought by local and state government entities, are pending that allege generally that EPI and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. These cases generally seek damages, treble damages, disgorgement of profits, restitution and attorneys fees.

The federal court cases have been or are in the process of being consolidated in the United States District Court for the District of Massachusetts under the Multidistrict Litigation Rules as *In re: Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456*. The following previously reported cases are pending in MDL 1456 and have been or will likely be consolidated into one consolidated complaint: *City of New York v. Abbott Laboratories, Inc., et al.*; *County of Albany v. Abbott Laboratories, Inc., et al.*; *County of Allegany v. Abbott Laboratories, Inc., et al.*; *County of Broome v. Abbott Laboratories, Inc., et al.*; *County of Cattaraugus v. Abbott Laboratories, Inc., et al*; *County of Cayuga v. Abbott Laboratories, Inc., et al.*; *County of Chautauqua v. Abbott Laboratories, Inc., et al.*; *County of Chenango v. Abbott Laboratories, Inc., et al.*; *County of Columbia v. Abbott Laboratories, Inc., et al.*; *County of Cortland v. Abbott Laboratories, Inc., et al.*; *County of Dutchess v. Abbott Laboratories, Inc., et al.*; *County of Essex v. Abbott Laboratories, Inc., et al.*; *County of Fulton v. Abbott Laboratories, Inc., et al.*; *County of Genesee v. Abbott Laboratories, Inc., et al.*; *County of Greene v. Abbott Laboratories, Inc., et al.*; *County of Herkimer v. Abbott Laboratories, Inc., et al.*; *County of Jefferson v. Abbott Laboratories, Inc., et al.*; *County of Lewis v. Abbott Laboratories, Inc., et al.*; *County of Madison v. Abbott Laboratories, Inc., et al.*; *County of Monroe v. Abbott Laboratories, Inc., et al.*; *County of Niagara v. Abbott Laboratories, Inc., et al.*; *County of Oneida v. Abbott Laboratories, Inc., et al.*; *County of Onondaga v. Abbott Laboratories, Inc., et al.*; *County of Ontario v. Abbott Laboratories,*

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Inc., et al.; *County of Orleans v. Abbott Laboratories, Inc., et al.*; *County of Putnam v. Abbott Laboratories, Inc., et al.*; *County of Rensselaer v. Abbott Laboratories, Inc., et al.*; *County of Rockland v. Abbott Laboratories, Inc., et al.*; *County of St. Lawrence v. Abbott Laboratories, Inc., et al.*; *County of Saratoga v. Abbott Laboratories, Inc., et al.*; *County of Schuyler v. Abbott Laboratories, Inc., et al.*; *County of Seneca v. Abbott Laboratories, Inc., et al.*; *County of Steuben v. Abbott Laboratories, Inc., et al.*; *County of Suffolk v. Abbott Laboratories, Inc., et al.*; *County of Tompkins v. Abbott Laboratories, Inc., et al.*; *County of Warren v. Abbott Laboratories, Inc., et al.*; *County of Washington v. Abbott Laboratories, Inc., et al.*; *County of Wayne v. Abbott Laboratories, Inc., et al.*; *County of Westchester v. Abbott Laboratories, Inc., et al*; and *County of Yates v. Abbott Laboratories, Inc., et al.*

Three additional New York counties represented by the same law firm as the counties described above filed lawsuits under seal in federal district court. Those lawsuits are: County of Chemung v. Abbott Laboratories, Inc., et al., filed in December 2005 in the United States District Court for the Western District of New York; County of Ulster v. Abbott Laboratories, Inc., et al., filed in January 2006 in the United States District Court for the Northern District of New York; and County of Wyoming v. Abbott Laboratories, Inc., et al., filed in December 2005 in the United States District Court for the Western District of New York. It is expected that these cases will be transferred to MDL 1456 and will join the cases described above in a consolidated complaint.

One previously reported case filed in state court and removed to federal court has been remanded back to state court: *County of Erie v. Abbott Laboratories, Inc., et al.*

There is a previously reported case pending in state court in Alabama against EPI and numerous other pharmaceutical companies: *State of Alabama v. Abbott Laboratories, Inc., et al.,* filed in January 2005 in the Circuit Court of Montgomery County.

There is a previously reported case pending in Mississippi against EPI and numerous other pharmaceutical companies: *State of Mississippi v. Abbott Laboratories, Inc., et al.*, filed in October, 2005 in the Chancery Court of Hinds County, Mississippi.

The Company intends to contest all of these cases vigorously. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against the Company.

Other Legal Proceedings

In addition to the above proceedings, we are involved in, or have been involved in, arbitrations or various other legal proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these claims and other proceedings. Currently, we are not involved in any arbitration and/or other legal proceeding that we expect to have a material effect on our business, financial condition, results of operations or cash flows.

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the fourth quarter of our fiscal year ended December 31, 2005.

PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information. Our common stock is traded on the NASDAQ under the symbol ENDP . The following table sets forth the quarterly high and low share price information for the periods indicated. The prices shown represent quotations between dealers, without adjustment for retail markups, markdowns or commissions, and may not represent actual transactions.

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	Endo Common Stock	
	High	Low
Year Ending December 31, 2005		
1st Quarter	$ 23.18	$ 19.52
2nd Quarter	$ 26.48	$ 19.02
3rd Quarter	$ 30.52	$ 25.11
4th Quarter	$ 31.93	$ 24.36
Year Ending December 31, 2004		
1st Quarter	$ 25.00	$ 18.78
2nd Quarter	$ 27.15	$ 20.34
3rd Quarter	$ 23.59	$ 15.78
4th Quarter	$ 22.78	$ 17.17

Holders. As of March 3, 2006, we estimate that there were approximately 105 record holders of our common stock.

Dividends. We have not declared or paid any cash dividends on our capital stock, and do not anticipate paying any cash dividends in the foreseeable future. Our credit facility contains limitations and restrictions on the payment of dividends.

Item 6. ***Selected Financial Data***

The consolidated financial data presented below have been derived from our audited financial statements. The selected historical consolidated financial data presented below should be read in conjunction with Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data. The selected data in this section is not intended to replace the consolidated financial statements. The information presented below is not necessarily indicative of the results of our future operations. Certain prior year amounts have been reclassified to conform to the current year presentation.

	Year Ended December 31,				
	2005	2004	2003	2002	2001
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Net sales	$ 820,164	$ 615,100	$ 595,608	$ 398,973	$ 251,979
Cost of sales	186,350	140,989	135,671	98,857	74,891
Gross profit	633,814	474,111	459,937	300,116	177,088
Selling, general and administrative	211,246	179,270	154,229	110,149	79,303
Research and development	88,307	51,476	52,622	57,581	39,196
Depreciation and amortization	15,497	10,630	6,272	3,142	49,234
Loss on disposal of other intangible		3,800			
Impairment of other intangible asset	5,515				
Compensation related to stock options (primarily, selling, general and administrative)			144,524	34,659	37,253
Purchased in-process research and development			(6,966)	20,300	

Manufacturing transfer fee				9,000	
Operating income (loss)	313,249	228,935	109,256	65,285	(27,898)
Interest (income) expense, net	(10,995)	(2,161)	258	4,391	13,290
Income (loss) before income tax (benefit)	324,244	231,096	108,998	60,894	(41,188)
Income tax (benefit)	121,949	87,787	39,208	30,081	(4,646)
Net income (loss)	$ 202,295	$ 143,309	$ 69,790	$ 30,813	$ (36,542)
Basic and Diluted Net Income (Loss) Per Share:					
Basic	$ 1.53	$ 1.09	$ 0.54	$ 0.30	$ (0.40)
Diluted	$ 1.52	$ 1.08	$ 0.53	$ 0.30	$ (0.40)
Shares Used to Compute Basic Net Income (Loss) Per Share	132,242	131,805	128,417	102,064	91,505
Shares Used to Compute Diluted Net Income (Loss) Per Share	133,289	132,718	132,439	102,126	91,505
Cash dividends declared per share					

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	As of and for the Year Ended December 31,				
	2005	2004	2003	2002	2001
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 500,956	$ 278,034	$ 229,573	$ 56,902	$ 95,357
Working capital	483,872	294,329	287,922	105,058	65,259
Total assets	1,371,678	947,491	753,880	512,972	470,995
Total debt					91,259
Other long-term obligations, including capitalized leases	18,795	18,293	589	7,851	207
Stockholders equity	843,370	655,950	567,617	352,692	295,122
Other Financial Data:					
Net cash provided by operating activities	$ 284,644	$ 170,545	$ 217,444	$ 110,029	$ 79,557
Net cash used in investing activities	(26,684)	(107,824)	(44,344)	(22,665)	(5,617)
Net cash used in financing activities	(35,038)	(14,260)	(429)	(125,819)	(37,779)

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

Except for the historical information contained in this Report, this Report, including the following discussion, contains forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements beginning on page 1 of this Report.

Overview

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to Wolters Kluwer Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled $18.7 billion in 2005. This represents an approximately 6% compounded annual growth rate since 2001. Our primary area of focus within this market is analgesics and, specifically, opioid analgesics. In 2005, analgesics were the fourth most prescribed medication in the United States with over 246 million prescriptions written for this classification. Opioid analgesics is a segment that comprised approximately 89% of the analgesics prescriptions for 2005. Total U.S. sales for the opioid analgesic segment were $8.2 billion in 2005, representing a compounded annual growth rate of 10% since 2001.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Frova®, Percodan® and DepoDur®. Branded products comprised approximately 71% of our net sales in 2005, with 51% of our net sales coming from Lidoderm®. Our non-branded generic portfolio, which accounted for 29% of net sales in 2005, currently consists of products primarily focused in pain management, with our generic oxycodone extended release accounting for 14% of our net sales in 2005. We focus on selective generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded product pipeline includes two filed New Drug Applications, or NDAs, three products in Phase III clinical trials and four products in Phase II clinical trials.

We enhance our financial flexibility by outsourcing certain of our functions, including manufacturing. Currently, our primary suppliers of contract manufacturing services are Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd.

Through a dedicated sales force of approximately 370 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, neurology, surgery, anesthesiology, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

On a continuous basis, we evaluate and, where appropriate, pursue acquisition opportunities on terms we consider favorable. In particular, we look to continue to enrich our product line by acquiring or licensing rights to additional products and compounds and therefore regularly evaluate selective acquisition and license opportunities. Such acquisitions or licenses may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. Currently, however, we have no binding commitment related to any acquisitions.

Our wholly owned subsidiary, Endo Pharmaceuticals Inc., commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became DuPont

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Pharmaceuticals Company and was thereafter purchased by the Bristol Myers Squibb Pharma Company in 2001. Endo Pharmaceuticals Inc. was formed by some members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement, under which we acquired these initial assets. We were incorporated in Delaware as a holding company on November 18, 1997.

Recent Developments

On March 9, 2005, we announced that Peter A. Lankau, the then current president and chief operating officer of Endo, had been appointed president and chief executive officer by our Board of Directors, effective May 20, 2005, the day following the Annual Meeting of Endo Stockholders. Carol A. Ammon, Endo s former chief executive officer, will continue to serve Endo as Chairman of the Board of Directors. In addition, Endo s Board of Directors had appointed Lankau to the Endo Board of Directors, effective March 9, 2005. This appointment expanded the number of directors to 11.

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a $10 million upfront fee, with additional payments of approximately $35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch.

Also on March 14, 2005, we announced that we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, in March 2005, we made a $10 million upfront payment and could be required to make additional payments of approximately $13.0 million for the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch.

On September 27, 2005, the U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven s Abbreviated New Drug Application for its developmental transdermal fentanyl patch based on the FDA s assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic®. As a result, we incurred a charge of approximately $4 million related to the write-off of our portion of the transdermal fentanyl patch inventory and an impairment charge of approximately $5.5 million, which represents the unamortized portion of the upfront license fee that we paid Noven in February 2004. On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

On December 22, 2005, we filed the complete responses to the U.S. Food and Drug Administration s approvable letters on the company s New Drug Applications (NDAs) for each of its investigational products oxymorphone extended-release (oxymorphone ER) and immediate-release (oxymorphone IR) tablets. As previously disclosed on October 20, 2003, the FDA issued approvable letters for oxymorphone ER and IR tablets but had requested that we address certain questions and provide more clarification and information, including data from additional clinical trials to further confirm the safety and efficacy of these products. Under the PDUFA guidelines, the FDA confirmed our six-month PDUFA date as

June 22, 2006, which is the date on which we expect to receive action letters from the FDA on these filings. If approved, we expect to launch oxymorphone ER and IR in the second half of 2006. Oxymorphone ER would compete in the market for long-acting, strong opioids. In order to meet the FDA s request for more clinical information for oxymorphone ER, we conducted two separate multi-center, randomized, double-blind, placebo-controlled, 12-week, parallel group trials evaluating this product in two distinct groups of patients with chronic low back pain: opioid-naive and opioid-experienced. These trials demonstrated statistically ($p<0.0001$) and clinically significant efficacy in these patient populations. The trial involving opioid-naive patients was conducted under the FDA s Special Protocol Assessment (SPA) process. We also reported that the complete response to the oxymorphone IR approvable letter included previously disclosed positive results for a placebo-controlled, multi-center Phase III trial for oxymorphone IR in the treatment of acute post-operative pain. Endo also conducted this

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study under the FDA s SPA process. The data from the two new oxymorphone ER Phase III studies and from the one oxymorphone IR Phase III study will supplement the previously submitted Phase III trials for both products that the company believes the FDA already has accepted as demonstrating efficacy in the intended patient populations.

On January 6, 2006, we announced the appointment of John J. Delucca to our Board of Directors. An independent, outside director, Mr. Delucca also has been appointed as a member of the audit committee of the Board of Directors. He replaces Frank J. Loverro, a managing director of Kelso & Company, who has been a member of the Board since July 2000 and who resigned on January 6, 2006. Mr. Delucca, 62, was executive vice president and chief financial officer of the REL Consultancy Group until his retirement in 2004. Prior to that, he served as chief financial officer and executive vice president, finance & administration, of Coty, Inc., from 1999 to 2002. From 1993 to 1999, he was senior vice president and treasurer of RJR Nabisco, Inc. During his career, he also served in executive positions for Hascoe Associates, Inc., The Lexington Group, the Trump Group, International Controls Corp., and Textron, Inc. Mr. Delucca is currently a non-executive director and chairs the audit committees of ITC Deltacom, Enzo Biochem, Inc. and The Elliot Company. He also serves as a non-executive director and deputy chairman of the audit committee of British Energy PLC.

In January 2006, the Company signed a license agreement with ZARS Pharma that will give it the exclusive North American rights to Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical patch. Under the terms of the agreement, the Company paid ZARS an upfront fee of $11 million, with additional payments of up to approximately $27 million upon achievement of certain commercial milestones, $8 million of which will be due upon the first commercial sale of the product, which is expected in the second half of 2006. The Company will also pay ZARS undisclosed royalties on net sales of Synera™. ZARS is a privately held company based in Salt Lake City, Utah, focused on the development and commercialization of patented technologies that deliver drugs into and across the skin. Synera™ is a topical local anesthetic patch for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the U.S. Food and Drug Administration on June 23, 2005, Synera™ is expected to become commercially available in the second half of 2006.

In January 2006, the Company completed a public offering of 15,000,000 shares of its common stock by certain of its shareholders. All of the shares were already issued and outstanding, except for approximately 40,000 shares representing shares underlying outstanding stock options. Endo Pharma LLC sold the majority of the shares being sold. Certain members of management have an ownership interest in Endo Pharma LLC. Shares were sold by management and certain members of the board of directors of the Company. Following completion of the offering, Endo Pharma LLC held approximately 8.0% of Endo s outstanding common stock.

On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo s favor by the U.S. District Court for the Southern District of New York on January 5, 2004, which found Purdue had committed inequitable conduct in the U.S. Patent and Trademark Office. This affirmance by the Federal Circuit Court dismissed the claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoined Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue s petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. On February 1, 2006, we announced that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmance of the Opinion and Order in our favor and affirmed the District Court s finding that, if Purdue s patents are enforceable, Endo s oxycodone extended-release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same District Court for its further consideration as to whether the Purdue patents are unenforceable. We intend to continue marketing our generic oxycodone extended-release tablets at this time. In the event there is a final nonappealable judgment that Purdue s patents are valid and enforceable, we could face substantial liability for patent infringement and be obligated to pay Purdue damages in an amount to be determined by the District Court. Although there can be no assurance, we believe that we would be able to fund the payment of these damages without materially adversely affecting our business operations, including our acquisition and licensing strategy. See Item 3. Legal Proceedings for further information. The U.S. Food and Drug Administration had previously granted final approval of our abbreviated new drug application (ANDA) for all four strengths of this product in 2004. Our oxycodone extended-release tablets are AB-rated bioequivalent versions of OxyContin®, a product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. All OxyContin® strengths, as well as generics of all strengths, had combined 2005 U.S. sales of approximately $1.8 billion. We launched

all four strengths of the product on June 7, 2005 and had net sales of $114.0 million for the year ended December 31, 2005.

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We have been advised by Brian T. Clingen and Michael W. Mitchell that they each intend to resign from our board of directors effective March 15, 2006, in order to devote more time to their respective current activities. In addition, Michael B. Goldberg and David I. Wahrhaftig, both managing directors of Kelso, have advised us that they also intend to resign from our board of directors effective on the same date; these resignations are consistent with Kelso s practice of not having its partners serve on the boards of directors of public companies unless Kelso s level of beneficial stock ownership in the company is significant and warrants such participation. Following such resignations, our board of directors will have seven board members, including John J. Delucca who was appointed on January 6, 2006 to replace Endo board member Frank J. Loverro, a managing director of Kelso, who resigned as a board member on that date. In order to ease this transition, we have underway an active process to identify persons qualified to serve as members of our board of directors and may propose such persons for election or appointment in the future.

Our quarterly and annual results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options, impairment of intangible assets, and upfront, milestone and certain other payments made or accrued pursuant to licensing agreements.

Critical Accounting Policies and Estimates

To understand our financial statements, it is important to understand our critical accounting policies and estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of capitalization and amortization periods for identifiable intangible assets, inventories and related inventory reserves and the potential impairment of goodwill and other intangible assets. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results may differ significantly from our estimates. Our most critical accounting policies and estimates are described below:

Sales Deductions

When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. These provisions are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be impacted. The provision for chargebacks is one of the most significant and the most complex estimate used in the recognition of our revenue. We establish contract prices for indirect customers who are supplied by our wholesale customers. A chargeback represents the difference between our invoice price to the wholesaler and the indirect customer s contract price. Provisions for estimating chargebacks are calculated primarily using historical chargeback experience, estimated wholesaler inventory levels and estimated future trends. We also establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives and other allowances. Some customers receive rebates upon attaining established sales volumes. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. We estimate an accrual for Medicaid rebates as a reduction of revenue at the time product sales are recorded. The Medicaid rebate reserve is estimated based upon the historical payment experience, historical relationship to revenues and estimated future trends. Medicaid pricing programs involve particularly difficult interpretations of statutes and regulatory guidance, which are complex and thus our estimates could differ from actual experience. Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties, payable to Hind, are recorded as a reduction to net sales due to the nature of the license agreement and

the characteristics of the license involvement by Hind in Lidoderm®. Royalties are paid to Hind at a rate of 10% of net sales of Lidoderm®. Our return policy allows customers to receive credit for expired products within three to six months prior to expiration and within one year after expiration. We estimate the provision for product returns based upon the historical experience of

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returns for each product, historical relationship to revenues, estimated future trends, estimated customer inventory levels and other competitive factors. We continually monitor the factors that influence each type of sales deduction and make adjustments as necessary. A table showing the activity of our most significant sales deductions is as follows (in thousands):

Year Ending December 31, 2005	Beginning Balance	Current provisions related to sales made during the year	Actual deductions during the year	Ending Balance
Chargebacks	$ 40,290	$ 325,392	$ (314,874)	$ 50,808
Returns	21,649	19,387	(19,821)	21,215
Rebates	50,773	183,461	(138,669)	95,565
Total	$ 112,712	$ 528,240	$ (473,364)	$ 167,588

Year Ending December 31, 2004	Beginning Balance	Current provisions related to sales made during the year	Actual deductions during the year	Ending Balance
Chargebacks	$ 28,304	$ 211,904	$ (199,918)	$ 40,290
Returns	22,698	24,194	(25,243)	21,649
Rebates	44,784	103,246	(97,257)	50,773
Total	$ 95,786	$ 339,344	$ (322,418)	$ 112,712

Inventories

Inventories consist of finished goods held for distribution, raw materials and work in process. Our inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results. Inventories also include costs associated with certain products prior to regulatory approval and/or resolution of patent infringement litigation based on management s judgment of probable future commercial use and net realizable value.

Goodwill and Other Intangibles

Goodwill and other intangibles represent a significant portion of our assets and stockholders equity. As of December 31, 2005, goodwill and other intangibles comprised approximately 20% of our total assets and 33% of our stockholders equity. SFAS No. 142, Goodwill and Other Intangible Assets, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit s fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit s goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. On January 1, 2006, 2005 and 2004, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from twelve to twenty years, with a weighted average useful life of approximately 16 years. The determination to capitalize amounts related to licenses is based on management s

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judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products and/or various other competitive factors. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty. During the year ended December 31, 2005, the Company expensed $20 million with respect to the acquisitions of marketing and development license rights for two products that are currently in development. We expensed the cost of these license rights based on the fact that we acquired both marketing and development rights for products that do not have regulatory approval and that do not have currently identifiable alternative future uses. As such, it was determined that the cost of the right to develop the products and the cost of the right to market the products were inextricably linked and therefore expensed in the accompanying financial statements. Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

Licenses and patents are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations.

Goodwill and other intangible assets consist of the following at December 31, 2005 and 2004, respectively (in thousands):

	2005	2004
Goodwill	$ 181,079	$ 181,079
Amortizable Intangibles:		
Licenses	$ 112,100	$ 123,600
Patents	3,200	3,200
	115,300	126,800
Less accumulated amortization	(16,235)	(9,542)
Other Intangibles, net	$ 99,065	$ 117,258

As of December 31, 2005, estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2005 is as follows (in thousands):

2006	$ 7,235
2007	7,235

2008	7,235
2009	7,235
2010	7,235

Income Taxes

Provisions for income taxes are calculated on reported pre-tax income based on current tax laws, statutory tax rates and available tax incentives and planning opportunities in various jurisdictions in which we operate. Such provisions differ from the amounts currently receivable or payable because certain items of income and expense are recognized in different time periods for financial reporting purposes than for income tax purposes. Significant judgment is required in determining income tax provisions and evaluating tax positions. We establish reserves for income tax when, despite the belief that our tax positions are fully supportable, there remain certain positions that may be challenged and possibly disallowed by various authorities. The tax provision and related accruals include the impact of such reasonably estimable losses as deemed appropriate.

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Contingencies

The Company is subject to various patent, product liability, government investigations and other legal proceedings in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses. Contingent accruals are recorded when the Company determines that a loss related to a litigation matter is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgments regarding future events.

Results of Operations

Net Sales

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for certain chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. We recognize revenue when products are shipped and title and risk of loss has passed to the customer, which is typically upon delivery to the customer. Our shipping terms are generally free on board customer s destination.

The following table presents our net sales by product category for the years ended December 31, 2005, 2004 and 2003.

	Year Ended December 31,		
	2005	2004	2003
	(in thousands)		
Lidoderm®	$ 419,418	$ 309,230	$ 178,299
Percocet®	110,700	86,510	214,187
Frova®	38,096	11,449	
DepoDur®	3,931		
Other brands	11,098	15,481	21,870
Total brands	583,243	422,670	414,356
Oxycodone extended release	113,969		
Other generics	122,952	192,430	181,252
Total generics	236,921	192,430	181,252
Total net sales	$ 820,164	$ 615,100	$ 595,608

The following table presents our net sales as a percentage of total net sales for select products for the years ended December 31, 2005, 2004 and 2003.

	Year Ended December 31,		
	2005	2004	2003
Lidoderm®	51%	50%	30%
Percocet®	13	14	36
Frova®	5	2	
DepoDur®	1		
Other brands	1	3	4
Total brands	71	69	70
Oxycodone extended release	14		
Other generics	15	31	30
Total generics	29	31	30
Total	100%	100%	100%

Year Ended December 31, 2005 Compared to the Year Ended December 31, 2004

Net Sales. Net sales for the year ended December 31, 2005 increased by 33% to $820.2 million from $615.1 million in the comparable 2004 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, Percocet®, our generic oxycodone extended release product, sales of which were not present in the comparable 2004 period, and Frova®. These increases were offset by the reduction in the sales of certain of our generic products. Net sales of Lidoderm® increased by 36% to

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$419.4 million from $309.2 million in the comparable 2004 period due to the continued prescription growth of the product. Percocet® net sales increased to $110.7 million from $86.5 million in the comparable 2004 period. Net sales of Frova® increased to $38.1 million from $11.4 million in the comparable 2004 period. We began shipping Frova® upon the closing of the license agreement in mid-August 2004 and initiated our promotional efforts in September 2004. Net sales of our generic products increased by 23% to $236.9 million from $192.4 million in the comparable 2004 period primarily due to the net sales of $114.0 million from our generic oxycodone extended release product, which we launched in June 2005, offset by the reduction in the net sales of our morphine sulfate extended release tablets and Endocet®, both of which experienced additional generic competition which has decreased both our market share as well as the price of these generic products. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. Due primarily to the expected increases in the net sales of Lidoderm® partially offset by generic competition with our generic oxycodone extended release tablets, Percocet®, Endocet® and morphine sulfate extended-release tablets, we expect net sales in 2006 to be approximately $860 to $880 million. There can be no assurance of Endo achieving these results.

Gross Profit. Gross profit for the year ended December 31, 2005 increased by 34% to $633.8 million from $474.1 million in the comparable 2004 period. Gross profit margins remained at 77% for the years ended December 31, 2005 and 2004.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2005 increased by 18% to $211.2 million from $179.3 million in the comparable 2004 period. The year-over-year increase is due to our continued investment in our commercial business and our infrastructure to support our products and pipeline, including the addition of approximately 115 sales representatives in early 2005 to promote our products Lidoderm®, Frova® and DepoDur®. During 2006, we anticipate our SG&A expenses will be higher than in 2005 as we increase our level of investment in educational and promotional activities as well as overall support of our business, including supporting the pre-launch activities for oxymorphone ER and IR.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2005 increased by 71% to $88.3 million from $51.5 million in the comparable 2004 period. This increase is primarily related to $20 million expensed during the year ended December 31, 2005 related to the upfront payments to license the topical ketoprofen patch and the transdermal sufentanil patch, $7.3 million in milestone payments, incurred during the year ended December 31, 2005, to Orexo related to Rapinyl™, our increased developmental efforts with respect to oxymorphone extended-release tablets and immediate-release tablets and the advancement of other recently acquired products partially offset by $10 million in milestone payments, incurred during the year ended December 31, 2004, to SkyePharma related to the FDA approval of DepoDur® and the advancement of Propofol IDD-D™ to the end of Phase II clinical development. Excluding milestone payments to partners, we anticipate increasing our research and development spending in 2006 over 2005, primarily for continuing clinical development of Rapinyl™, our topical ketoprofen patch and our transdermal sufentanil patch.

Depreciation and Amortization. Depreciation and amortization for the year ended December 31, 2005 increased to $15.5 million from $10.6 million in the comparable 2004 period primarily due to an increase in amortization expense as a result of new license rights acquired during 2004 and an increase in depreciation expense as a result of an increase in capital expenditures. We expect depreciation and amortization to continue to increase as we increase our capital expenditures for new office and lab space and automobiles for our newly hired sales representatives, and as we continue to license in products and technologies.

Loss on Disposal of Other Intangible. For the year ended December 31, 2004, the loss on disposal of other intangible is due to the termination of our collaboration agreement with Lavipharm and the resulting write-off of the unamortized portion of the upfront license fee of $0.8 million. The loss also includes a $3 million termination payment made by us to Lavipharm.

Impairment of Other Intangible Asset. For the year ended December 31, 2005, the impairment of other intangible assets is due to the FDA s decision not to approve Noven s Abbreviated New Drug Application for its developmental transdermal fentanyl patch and represents the

unamortized portion of the upfront license fee that we paid Noven in February 2004.

Interest (Income) Expense, Net. Interest income, net for the year ended December 31, 2005 was $11.0 million compared to $2.2 million in the comparable 2004 period. This increase is substantially due to a full year of interest income earned on our note receivable from Vernalis in 2005 compared to a partial period of interest income earned on the note receivable from Vernalis in 2004, as the funds were loaned to Vernalis in August 2004, as well as increased interest income earned as a result higher average cash balances during 2005.

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Income Tax. Income tax for the year ended December 31, 2005 increased to $121.9 million from $87.8 million in the comparable 2004 period. This increase is due to the increase in income before income tax for the year ended December 31, 2005 partially offset by a decrease in the effective tax rate from 38.0% in 2004 to 37.6% in 2005.

Year Ended December 31, 2004 Compared to the Year Ended December 31, 2003

Net Sales. Net sales for the year ended December 31, 2004 increased by 3% to $615.1 million from $595.6 million in the comparable 2003 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, net sales of Frova®, and an increase in the net sales certain generic products offset by the reduction in the net sales of Percocet®. Net sales of Lidoderm® increased to $309.2 million from $178.3 million in the comparable 2003 period. Net sales of Frova® were $11.4 million for the year ended December 31, 2004. We began shipping Frova® upon the closing of the license agreement in mid-August 2004 and initiated our promotional efforts in September 2004. Net sales of our generic products increased to $192.4 million from $181.3 million in the comparable 2003 period primarily due to the increase in the net sales of Endocet® as a result of our launch in the fourth quarter of 2003 of two new strengths of Endocet® offset by a decrease in the net sales of our morphine sulfate extended-release tablets as a result of generic competition introduced in the fourth quarter of 2003. During the second half of 2004, we began to experience both pricing pressure as well as a reduction in our share for both Endocet® and our morphine sulfate extended-release tablets due to generic competition. Percocet® net sales decreased to $86.5 million from $214.2 million in the comparable 2003 period due to the introduction of generic versions of Percocet® 7.5/325 and 10/325 during the fourth quarter of 2003.

Gross Profit. Gross profit for the year ended December 31, 2004 increased by 3% to $474.1 million from $459.9 million in the comparable 2003 period. Gross profit margins remained at 77% for the years ended December 31, 2004 and 2003. The gross profit margin for 2003 includes a charge of $24.6 million to fully reserve for the inventory of extended-release oxycodone tablets that were manufactured during that year. Pricing pressures on our generic products, combined with the introduction in April 2004 of more costly single-pouch child-resistant packaging for Lidoderm® were the primary factors affecting the gross profit margin for the year ended December 31, 2004.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for the year ended December 31, 2004 increased by 16% to $179.3 million from $154.2 million in the comparable 2003 period. This increase was due to an increase in sales, education and promotional efforts in 2004 over the comparable 2003 period to support our products as well as support for our growing business including our products Lidoderm®, Frova® and DepoDur®, and in preparation of new product launches.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2004 decreased by $1.1 million to $51.5 million compared to $52.6 million in the comparable 2003 period.

Depreciation and Amortization. Depreciation and amortization for the year ended December 31, 2004 increased to $10.6 million from $6.3 million in the comparable 2003 period primarily due to an increase in amortization expense as a result of new license rights acquired during 2004 and an increase in depreciation expense as a result of an increase in capital expenditures.

Compensation Related to Stock Options. Compensation related to stock options for the year ended December 31, 2004 decreased to $0 from $144.5 million in the comparable 2003 period. Effective January 1, 2003, the Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately $48.5 million in the first quarter of 2003 representing the difference between the market price of the common stock of $7.70 and the exercise price of these stock options of $2.42. In addition, we recorded a non-cash compensation charge of $96.0 million in October 2003 as

a result of the vesting of the 4.8 million Class C4 stock options representing the difference between the market price of the common stock of $22.59 and the exercise price of these options of $2.63. No additional shares of our common stock have been or will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, the exercise of these stock options does not dilute the ownership of our other public stockholders.

Purchased In-Process Research and Development. Purchased in-process research and development during the year ended December 31, 2003 reflects a gain of $7.0 million related to the extinguishment of a contingent liability as a result of our decision to discontinue our development program for the oral rinse (0.1% triclosan) for the treatment of oral mucositis that we had obtained in the acquisition of BML Pharmaceuticals in July 2002.

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Interest (Income) Expense, Net. Interest (income) expense, net for the year ended December 31, 2004 was $2.2 million in interest income compared to $0.3 million in interest expense in the comparable 2003 period. This change is substantially due to the increased interest income earned as a result of higher average cash balances during 2004 and interest income earned on our note receivable from Vernalis.

Income Tax. Income tax for the year ended December 31, 2004 increased to $87.8 million from $39.2 million in the comparable 2003 period. This increase is due to the increase in income before income tax for the year ended December 31, 2004 as well as an increase in the effective tax rate from 36.0% in 2003 to 38.0% in 2004. The effective tax rate in 2003 was favorably impacted by the recognition of a gain of $7.0 million in 2003 related to the reversal of a contingent liability related to the BML acquisition which had no tax impact.

Liquidity and Capital Resources

Our principal source of liquidity is cash generated from operations. Under our credit facility, we may borrow up to $75.0 million on a revolving basis for certain purposes as described below. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses, milestone payments and capital expenditures.

Net Cash Provided by Operating Activities. Net cash provided by operating activities increased to $284.6 million for the year ended December 31, 2005 from $170.5 million for the year ended December 31, 2004. Significant components of the $284.6 million of operating cash flows for the year ended December 31, 2005 included net income of $202.3 million, tax benefits of stock options exercised of $206.2 million, increases in accounts payable and accrued expenses of $78.3 million and a decrease in inventory of $20.4 million partially offset by a $146.8 million increase in accounts receivable primarily due to the timing and volume of net sales during the year ended December 31, 2005, and an increase in income taxes receivable of $68.3 million.

Net Cash Used in Investing Activities. Net cash used in investing activities decreased to $26.7 million for the year ended December 31, 2005 from $107.8 million for the year ended December 31, 2004. During the year ended December 31, 2005, the Company made a $14.5 million payment to Vernalis for the acquisition of the product rights to Frova®, paid $10.5 million for capital expenditures and invested $1.7 million in a limited partnership. During the year ended December 31, 2004, the Company loaned $50 million to Vernalis, paid $46.5 million in license fees, paid a termination penalty of $3 million to Lavipharm, invested $0.5 million in a limited partnership and had capital expenditures of $8.1 million primarily related to our new research and development facility in Long Island, New York.

Net Cash Used in Financing Activities. Net cash used in financing activities increased to $35.0 million for the year ended December 31, 2005 from $14.3 million for the year ended December 31, 2004. The increase is primarily due to a $42.8 million payment to Endo Pharma LLC pursuant to the tax sharing agreement and an increase in capital lease obligation repayments partially offset by an increase in the proceeds received from the exercise of employee stock options.

Credit Facility. In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of $75.0 million. The line of credit expires on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, including a covenant requiring us to maintain minimum EBITDA of $50 million over the prior four-quarter period, events of default and other provisions customarily found in similar agreements. Our ability to borrow under the credit facility is dependent, among other things, on our compliance with those provisions. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million

currently issued and outstanding shares of our common stock. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. As of December 31, 2005, we have not borrowed any amounts under our credit facility.

Tax Sharing Agreement. On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Endo Pharma LLC is a limited liability company that held approximately 15% of our common stock at December 31, 2005, in which affiliates of Kelso & Company and certain members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC have been and will be delivered. Because Endo Pharma LLC, and not us, has been and will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo

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Pharma LLC the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of December 31, 2005, approximately 32.7 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of December 31, 2005, approximately $669 million), which is estimated to result in a tax benefit amount of approximately $257 million. Under the tax sharing agreement, we are required to pay this $257 million, $56 million of which has already been paid as of December 31, 2005, to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 32.7 million options discussed above. We have paid approximately $9.9 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately $6.1 million, which represents the after-tax employer payroll tax expensed by us for the periods from 2001 through 2005.

On April 30, 2004, the tax sharing agreement was amended to provide for a specific schedule upon which payments currently contemplated by the tax sharing agreement would be made. The amended tax sharing agreement provides that the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i) 50% of the estimated amount shall be paid within 15 business days of our receipt from our independent registered public accounting firm of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return.

In 2004, we paid $13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. Since 6.6 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offerings on August 9, 2004 and November 29, 2004, at prices of $17.46 and $20.02, respectively, with a weighted average exercise price of $2.44, and an assumed tax rate of 38.7%, we were obligated to pay Endo Pharma LLC a tax benefit of approximately $41 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and other Endo Pharma LLC stock option exercises in 2004, aggregating $21.4 million, was due and was paid within 15 business days of the date we received an opinion on our audited 2004 financial statements from our independent registered public accounting firm and the remaining fifty percent of the tax benefit amount attributable to 2004 was due within 30 business days of the date on which we filed our 2004 tax return with the Internal Revenue Service (which occurred in September 2005) and approximately $21.4 million was paid in October 2005 to satisfy the tax sharing obligations attributable to 2004. As of December 31, 2005, approximately $200.9 million is payable to Endo Pharma LLC related to estimated tax sharing payments that we are obligated to pay which are attributable to 2005. This amount will be offset by the $6.1 million after-tax employer payroll amount discussed above. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders equity in the accompanying financial statements. The estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in the future.

On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14 and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9, 2004 and November 29, 2004 offerings, which totaled 19 million shares, up to 11 million shares remained eligible for sale by Endo Pharma LLC under this shelf registration statement. On September 2, 2005, we filed another registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission on September 26, 2005. This shelf registration statement, as amended, effectively increased the shares available for sale by Endo Pharma LLC from 11 million shares to up to 33.35 million currently issued and outstanding shares of our common stock. All of the shares available under this registration statement were sold pursuant to an offering on October 12, 2005, as discussed below. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future.

The Class C Endo Pharma LLC stock options (all of which were vested) became exercisable at the earlier of an exit event, as defined, or January 1, 2006. If the Class C stock options were not exercised by January 1, 2006, they would have terminated. Although the Company had considered extending the term of the Class C stock options, following enactment of the 2004 American Jobs Creation Act, an extension of the

term of the stock options would result in adverse tax consequences for the option holders. As a result, the Company and Endo Pharma LLC decided to accelerate the exercisability of the Class C stock options to allow approximately 22 million Class C stock options to be exercised before their expiration on January 1, 2006. The exercise of the Class C stock options is expected to generate a significant tax deduction for the Company and create a significant tax sharing payment obligation to Endo Pharma LLC pursuant to the tax sharing agreement. Upon exercise, option holders will receive shares of Company

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common stock currently owned by Endo Pharma LLC. Accordingly, no shares of Company common stock will be issued upon exercise of the Class C stock options.

On October 12, 2005, as part of the sale of 33,350,000 shares of our common stock, approximately 19.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised at a market price of $26.04, with a weighted average exercise price of $2.72, and an assumed tax rate of 38.4%. Since the attributable compensation charge deductions are usable to reduce our taxes in 2005, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately $175 million. Fifty percent of the estimated tax benefit amount attributable to the October 12, 2005 offering and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2005 will be due within 15 business days of the date we receive an opinion on our final audited 2005 financial statements from our independent registered public accounting firm and the remaining tax benefit amount attributable to 2005 is due within 30 business days of the date on which we file our 2005 tax return with the Internal Revenue Service. Additionally, since approximately 2.7 million additional stock options granted under the Endo Pharma LLC stock option plans were exercised during the year ended December 31, 2005, and since the attributable compensation charge deductions are usable to reduce our taxes in 2005, we will be obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately $26 million in 2006. As a result of the significant tax deductions expected to be generated in 2005 from the exercise of the 22.2 million stock options discussed above, we have incurred a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of a portion of prior years payments during 2006. All payments that have been, or will be, made or accrued pursuant to the tax sharing agreement have been, or will be, reflected as a reduction of stockholders equity in our consolidated financial statements. As of December 31, 2005, there are approximately 2.8 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of $2.42 per share and an assumed tax rate of 38.4%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was $30.26 per share the closing price on December 30, 2005, we would generally be able to deduct, for income tax purposes, compensation of approximately $78 million, which could result in a tax benefit amount of approximately $30 million payable to Endo Pharma LLC in 2007 and beyond.

Settlement of Contingent Obligation. During the year ended December 31, 2005, the Company reached an agreement with an individual to compensate him a total of $2 million for past services rendered to the Company. This agreement was finalized in May 2005, and the $2 million has been recorded in selling, general and administrative expenses during the year ended December 31, 2005. Endo Pharma LLC made these payments totaling $2 million on behalf of the Company, and they have been treated as a capital contribution by Endo Pharma LLC.

Fluctuations. Our quarterly and annual results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products and the impact of competitive products and pricing. Further, a substantial portion of our net sales are through wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

Growth Opportunities. We continue to evaluate growth opportunities including strategic investments, licensing arrangements and acquisitions of product rights or technologies, which could require significant capital resources.

Non-U.S. Operations. We currently have no operations outside of the United States. As a result, fluctuations in foreign currency exchange rates do not have a material effect on our financial statements.

Inflation. We do not believe that inflation had a material adverse effect on our financial statements for the periods presented.

Off-Balance Sheet Arrangements. We have no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

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Expected Cash Requirements for Contractual Obligations. The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2005 (in thousands):

	Payment Due by Period						
Contractual Obligations	**Total**	**2006**	**2007**	**2008**	**2009**	**2010**	**Thereafter**
Operating Lease Obligations	$ 22,104	$ 2,873	$ 2,727	$ 2,733	$ 2,740	$ 2,942	$ 8,089
Capital Lease Obligations	4,941	2,881	1,592	460	8		
Minimum Purchase Commitments to Teikoku	18,000	18,000					
Minimum Purchase Commitments to Novartis	31,040	7,760	7,760	7,760	7,760		
Estimated Tax Sharing Payments Due to Endo Pharma LLC	194,826	194,826					
License Payments Due to Vernalis	15,000	15,000					
Limited Partnership Commitment(1)	7,300	7,300					
Total	$ 293,211	$ 248,640	$ 12,079	$ 10,953	$ 10,508	$ 2,942	$ 8,089

(1) On December 12, 2003, we entered into a subscription agreement to invest up to $10 million into Life Sciences Opportunities Fund (Institutional) II, L.P., a Delaware limited partnership formed to carry out investments in life science companies. As of December 31, 2005, we have invested $2.7 million in this partnership.

In addition, we agreed to certain contingent payments in certain of our license, collaboration and other agreements. Payments under these agreements generally become due and payable only upon the achievement of certain developmental, regulatory, commercial and/or other milestones. Due to the fact that it is uncertain if and when these milestones will be achieved, such contingencies have not been recorded in our consolidated balance sheet.

Cash and Cash Equivalents. Our cash and cash equivalents totaled $501.0 million at December 31, 2005. We believe that our (a) cash and cash equivalents, (b) cash flow from operations and (c) our credit facility (which has an available unused line of credit of $75 million) will be sufficient to meet our normal operating, investing and financing requirements in the foreseeable future, including the funding of our pipeline projects in the event that our collaboration partners are unable or unwilling to fund their portion of any particular project. We may use a portion of our cash and cash equivalents for possible acquisitions and licensing opportunities.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4.* The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS No. 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of so abnormal. In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provision of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 is not expected to have a material impact on the Company s results of operations or financial position.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29.* SFAS No. 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005, with earlier application permitted. The adoption of SFAS No. 153 is not expected to have a material impact on the Company s results of operations or financial position.

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payments (revised 2004)*. This statement eliminates the option to apply the intrinsic value measurement provisions of APB Board Opinion No. 25, *Accounting for Stock Issued to Employees*, to stock compensation awards issued to employees. Rather, the Statement requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award the requisite service period (usually the vesting period). In March 2005, the SEC staff expressed their views with respect to SFAS No. 123R in Staff Accounting Bulletin No. 107, *Share-Based Payment*, (SAB 107). SAB 107 provides guidance on valuing options. SFAS No. 123R will be effective for the Company s fiscal year beginning January 1, 2006. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

In March 2005, the FASB issued FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations*, (FIN 47). FIN 47 is an interpretation of SFAS No. 143, *Asset Retirement Obligations*, which was issued in June 2001. FIN 47 was issued to address diverse accounting practices that have developed with regard to the timing of liability recognition for legal obligations associated with the retirement of a tangible long-lived asset in which the timing and/or method of settlement are conditional on a future event that may or may not be within the control of the entity. According to FIN 47, uncertainty about the timing and/or method of settlement of a conditional asset retirement obligation should be factored into the measurement of the liability when sufficient information exists. FIN 47 also clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 was adopted on December 31, 2005 by the Company and its adoption had no impact on our financial statements.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections,* a replacement of APB Opinion No. 20 and Statement No. 3. SFAS 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 is effective for accounting changes and corrections of errors made in

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fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on the Company s results of operations or financial position.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

Foreign Currency Risk

While all of our net sales are within the United States and denominated in U.S. dollars, we purchase Lidoderm®, in U.S. dollars, from Teikoku Seiyaku Co., Ltd., a Japanese manufacturer. As part of the purchase agreement with Teikoku, there is a price adjustment feature that prevents the cash payment in U.S. dollars from falling outside of a certain pre-defined range in Japanese yen even if the spot rate is outside of that range. A 10% change in foreign currency exchange rates would not have a material impact on our financial condition, results of operations or cash flows.

Interest Rate Risk

The primary objective of our investment of cash surpluses is the protection of principal and, accordingly, we invest in taxable and tax-free money market funds with relatively short maturities. Therefore, our investment of cash surpluses is not subject to significant interest rate risk.

On December 21, 2001, we entered into a new credit facility that provides for a line of credit of $75.0 million. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. Borrowings under the new credit facility are variable rate borrowings. There are no amounts outstanding under the new credit facility. We do not utilize financial instruments for trading purposes and hold no derivative financial instruments that could expose us to significant market risk. We monitor interest rates and enter into interest rate agreements as considered appropriate.

As of December 31, 2005 and December 31, 2004, we have no other assets or liabilities that have significant interest rate sensitivity.

Investment Risk

At December 31, 2005, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling $7.8 million in Other assets. The fair value of this investment is subject to significant fluctuations due to the volatility of the stock market, changes in general economic conditions and changes in the financial condition of DURECT. Based on the fair value of the publicly traded equity securities we held at December 31, 2005, an assumed 25%, 40% and 50% adverse change in the market prices of this security would result in a corresponding decline in total fair value of approximately $1.9 million, $3.1 million and $3.9 million, respectively.

Inflation

We do not believe that inflation has had a significant impact on our revenues or operations.

Item 8. ***Financial Statements and Supplementary Data***

The information required by this item is contained in the financial statements set forth in Item 15(a) under the caption Consolidated Financial Statements as part of this Annual Report on Form 10-K.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

Disclosure Controls and Procedures

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Our management, including our Chief Executive Officer and Chief Financial Officer, has conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective for timely gathering, analyzing and disclosing the information we are required to disclose in our reports filed with the SEC under the Securities Exchange Act of 1934, as amended.

Internal Control Over Financial Reporting

In addition, we evaluated our internal control over financial reporting, and there have been no changes in our internal control over financial reporting that occurred during the fourth quarter of 2005 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management s report on our internal control over financial reporting is included on page F-2. The report of our independent registered public accounting firm related to management s assessment of the effectiveness of internal control over financial reporting is included on page F-4.

Item 9B. ***Other Information***

Not applicable.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

Directors

The information concerning our directors required under this Item is incorporated herein by reference from our proxy statement, which will be filed with the Securities and Exchange Commission, relating to our Annual Meeting of Stockholders (our 2006 Proxy Statement).

Executive Officers

For information concerning Endo s executive officers, see Item 1. Business Executive Officers of the Registrant.

Code of Ethics

The information concerning our Code of Conduct is incorporated herein by reference from our 2006 Proxy Statement.

Audit Committee

The information concerning our Audit Committee is incorporated herein by reference from our 2006 Proxy Statement.

Audit Committee Financial Experts

The information concerning our Audit Committee Financial Experts is incorporated herein by reference from our 2006 Proxy Statement.

Item 11. ***Executive Compensation***

The information required under this Item is incorporated herein by reference from our 2006 Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

Equity Compensation Plan Information. The following information relates to plans in effect as of December 31, 2005 under which equity securities of Endo may be issued to employees and directors. Although the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans provide that stock options may be granted thereunder to non-employee consultants, Endo has never granted any such options to any such consultants.

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Plan Category	Column A Number of securities to be issued upon exercise of outstanding options, warrants and rights	Column B Weighted-average exercise price of outstanding options, warrants and rights	Column C Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)
Equity compensation plans approved by security holders			
Endo Pharma LLC Amended and Restated 1997 Executive Stock Option Plan	2,644,525(a)	$ 2.42	809,711(b)
Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan	164,740(a)	$ 2.42	809,711(b)
Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan	2,786,583	$ 13.54	171,277
Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan	512,847	$ 21.51	3,480,472
Equity compensation plans not approved by security holders			
Not Applicable.			

(a) All of the stock options granted under these plans are exercisable solely for shares currently held by Endo Pharma LLC (an affiliate of Kelso & Company in which certain members of management have an interest), and their exercise will not dilute the ownership of our other common stockholders.

(b) These shares are available for future issuance under either the Endo Pharma LLC Amended and Restated 1997 Executive Stock Option Plan or the Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan, but not both.

The other information required under this Item is incorporated herein by reference from our 2006 Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions***

The information required under this Item is incorporated herein by reference from our 2006 Proxy Statement.

Item 14. ***Principal Accounting Fees and Services***

Information about the fees for 2005 and 2004 for professional services rendered by our independent registered public accounting firm is incorporated herein by reference from our 2006 Proxy Statement. Our Audit Committee s policy on pre-approval of audit and permissible non-audit services of our independent registered public accounting firm is incorporated by reference from our 2006 Proxy Statement.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

Documents filed as part of this Annual Report on Form 10-K

1. Consolidated Financial Statements: See accompanying Index to Consolidated Financial Statements.

2. Consolidated Financial Statement Schedule:

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SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

(dollars in thousands)

	Balance at Beginning of Period	Additions, Costs and Expenses	Deductions, Write-offs	Balance at end of period
Allowance For Doubtful Accounts:				
Year Ended December 31, 2003	$ 835	$ 339	$ (68)	$ 1,106
Year Ended December 31, 2004	$ 1,106	$ 341	$	$ 1,447
Year Ended December 31, 2005	$ 1,447	$ 28	$	$ 1,475
Inventory Reserves:				
Year Ended December 31, 2003	$ 9,315	$ 14,703	$ (558)	$ 23,460
Year Ended December 31, 2004	$ 23,460	$ 3,985	$ (17,994)	$ 9,451
Year Ended December 31, 2005	$ 9,451	$ 1,312	$ (6,450)	$ 4,313

All other financial statement schedules have been omitted because they are not applicable or the required information is included in the Consolidated Financial Statements or notes thereto.

3. Exhibits: The information called for by this item is incorporated by reference to the Exhibit Index of this Report.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ENDO PHARMACEUTICALS HOLDINGS INC.
(Registrant)

/S/ Jeffrey R. Black
Name: Jeffrey R. Black
Title: *Executive Vice President and Chief Financial Officer*

Date: March 8, 2006

Pursuant to the requirements of the Securities Exchange of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ Peter A. Lankau Peter A. Lankau	President, Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2006
/S/ Jeffrey R. Black Jeffrey R. Black	Executive Vice President, Chief Financial Officer & Treasurer (Principal Financial & Accounting Officer)	March 8, 2006
* Carol A. Ammon	Chairman and Director	March 8, 2006
* Brian T. Clingen	Director	March 8, 2006
* Michael B. Goldberg	Director	March 8, 2006
* Michael Hyatt	Director	March 8, 2006

Roger H. Kimmel		
*	Director	March 8, 2006
John J. Delucca		
*	Director	March 8, 2006
Clive A. Meanwell, M.D., Ph.D.		
*	Director	March 8, 2006
Michael W. Mitchell		
*	Director	March 8, 2006
Joseph T. O Donnell, Jr.		
*	Director	March 8, 2006
David I. Wahrhaftig		
*By: /S/ Caroline B. Manogue	Attorney-in-fact, pursuant to a Power of Attorney filed with this Report as Exhibit 24	March 8, 2006
Caroline B. Manogue		

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INDEX TO FINANCIAL STATEMENTS

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MANAGEMENT S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Endo Pharmaceuticals Holdings Inc. is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Endo Pharmaceuticals Holdings Inc. s internal control system was designed to provide reasonable assurance to the company s management and board of directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Endo Pharmaceuticals Holdings Inc. s management assessed the effectiveness of the company s internal control over financial reporting as of December 31, 2005. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on our assessment we believe that, as of December 31, 2005, the company s internal control over financial reporting is effective based on those criteria.

Endo Pharmaceuticals Holdings Inc. s independent registered public accounting firm has issued an attestation report on our assessment of the company s internal control over financial reporting. This report appears on page F-4.

/S/ Peter A. Lankau
Peter A. Lankau
President, Chief Executive Officer and Director (Principal Executive Officer)

/S/ Jeffrey R. Black
Jeffrey R. Black
Executive Vice President, Chief Financial Officer & Treasurer (Principal Financial & Accounting Officer)

March 1, 2006

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Endo Pharmaceuticals Holdings Inc.

Chadds Ford, Pennsylvania

We have audited the accompanying consolidated balance sheets of Endo Pharmaceuticals Holdings Inc. and subsidiaries (the Company) as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders equity and comprehensive income, and cash flows for each of the three years in the period ended December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Endo Pharmaceuticals Holdings Inc. and subsidiaries as of December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of December 31, 2005, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2006 expressed an unqualified opinion on management s assessment of the effectiveness of the Company s internal control over financial reporting and an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania
March 1, 2006

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Endo Pharmaceuticals Holdings Inc.

Chadds Ford, Pennsylvania

We have audited management s assessment, included in the accompanying Management s Report on Internal Control over Financial Reporting, that Endo Pharmaceuticals Holdings Inc. and subsidiaries (the Company) maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2005 of the Company and our report dated March 1, 2006 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania

March 1, 2006

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ENDO PHARMACEUTICALS HOLDINGS INC.

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2005 AND 2004

(In thousands, except share data)

	2005	2004
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 500,956	$ 278,034
Accounts receivable, net of allowance of $1,475 and $1,447 at December 31, 2005 and 2004, respectively	290,826	139,039
Income taxes receivable	66,461	
Inventories, net	50,983	71,415
Prepaid expenses and other current assets	14,445	11,867
Deferred income taxes	69,714	67,222
Total current assets	993,385	567,577
PROPERTY AND EQUIPMENT, Net	38,001	28,875
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	99,065	117,258
NOTE RECEIVABLE, including accrued interest of $3,472 and $834 at December 31, 2005 and 2004, respectively	48,925	45,047
OTHER ASSETS	11,223	7,655
TOTAL ASSETS	$ 1,371,678	$ 947,491
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 94,787	$ 83,259
Accrued expenses	214,276	145,214
Due to Endo Pharma LLC	200,450	42,939
Income taxes payable		1,836
Total current liabilities	509,513	273,248
DEFERRED INCOME TAXES	14,637	1,664
OTHER LIABILITIES	4,158	16,629
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY:		
Preferred Stock, $0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, $0.01 par value; 175,000,000 shares authorized; 132,800,873 and 131,856,014 shares issued and outstanding at December 31, 2005 and 2004, respectively	1,328	1,319
Additional paid-in capital	619,336	635,915
Retained earnings	220,992	18,697
Accumulated other comprehensive income	1,714	19
Total stockholders equity	843,370	655,950

TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 1,371,678	$ 947,491

See notes to consolidated financial statements.

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ENDO PHARMACEUTICALS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003

(In thousands, except per share data)

	2005	2004	2003
NET SALES	$ 820,164	$ 615,100	$ 595,608
COST OF SALES[(a)]	186,350	140,989	135,671
GROSS PROFIT	633,814	474,111	459,937
COSTS AND EXPENSES:			
Selling, general and administrative	211,246	179,270	154,229
Research and development	88,307	51,476	52,622
Depreciation and amortization	15,497	10,630	6,272
Loss on disposal of other intangible, including license termination fee of $3,000		3,800	
Impairment of other intangible asset	5,515		
Compensation related to stock options (primarily selling, general and administrative)			144,524
Purchased in-process research and development			(6,966)
OPERATING INCOME	313,249	228,935	109,256
INTEREST (INCOME) EXPENSE, Net of interest (expense) income of $(1,744), $(1,255) and $660, respectively	(10,995)	(2,161)	258
INCOME BEFORE INCOME TAX	324,244	231,096	108,998
INCOME TAX	121,949	87,787	39,208
NET INCOME	$ 202,295	$ 143,309	$ 69,790
NET INCOME PER SHARE:			
Basic	$ 1.53	$ 1.09	$ 0.54
Diluted	$ 1.52	$ 1.08	$ 0.53
WEIGHTED AVERAGE SHARES			
Basic	132,242	131,805	128,417
Diluted	133,289	132,718	132,439

[(a)] Exclusive of amortization of intangible assets.

See notes to consolidated financial statements.

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ENDO PHARMACEUTICALS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME

YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003

(In thousands, except share data)

	Number Of Shares	Common Stock at Par Value	Additional Paid-in Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity	Comprehensive Income
BALANCE, JANUARY 1, 2003	102,064,450	$ 1,021	$ 547,249	$ (194,402)	$ (1,176)	$ 352,692	
Issuance of Common Stock from exercise of warrants	29,687,602	297	(296)			1	
Compensation related to stock options			144,524			144,524	
Exercise of options	17,714		154			154	
Unrealized gain on securities, net of tax					456	456	456
Net income				69,790		69,790	69,790
Comprehensive income							$ 70,246
BALANCE, DECEMBER 31, 2003	131,769,766	$ 1,318	$ 691,631	$ (124,612)	$ (720)	$ 567,617	
Tax sharing distributions made to Endo Pharma LLC			(13,549)			(13,549)	
Estimated tax sharing distributions due to Endo Pharma LLC			(42,939)			(42,939)	
Exercise of options	86,248	1	772			773	
Unrealized gain on securities, net of tax					739	739	739
Net income				143,309		143,309	143,309
Comprehensive income							$ 144,048
BALANCE, DECEMBER 31, 2004	131,856,014	$ 1,319	$ 635,915	$ 18,697	$ 19	$ 655,950	
Estimated tax sharing distributions due to Endo Pharma LLC			(194,662)			(194,662)	

Selling, general and administrative expenses funded by Endo Pharma LLC			2,000			2,000	
Exercise of options	944,859	9	10,180			10,189	
Tax benefits of stock options exercised			165,903			165,903	
Unrealized gain on securities, net of tax					1,695	1,695	1,695
Net income				202,295		202,295	202,295
Comprehensive income							$ 203,990
BALANCE, DECEMBER 31, 2005	132,800,873	$ 1,328	$ 619,336	$ 220,992	$ 1,714	$ 843,370	

See notes to consolidated financial statements.

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ENDO PHARMACEUTICALS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003

(In thousands)

	2005	2004	2003
OPERATING ACTIVITIES:			
Net income	$ 202,295	$ 143,309	$ 69,790
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	15,497	10,630	6,272
Purchased in-process research and development			(6,966)
Accretion of interest on note receivable	(1,240)	(413)	
Deferred income taxes	(30,894)	6,829	(64,244)
Tax benefits of stock options exercised	206,228	43,345	10,470
Amortization of deferred financing costs	383	390	398
Compensation related to stock options			144,524
Loss on disposal of other intangible		3,800	
Impairment of other intangible asset	5,515		
Loss on disposal of property and equipment	290	248	
Selling, general and administrative expenses funded by Endo Pharma LLC	2,000		
Changes in assets and liabilities which provided (used) cash:			
Accounts receivable	(146,787)	(37,755)	18,212
Inventories	20,432	(20,965)	(14,934)
Note receivable	(2,638)	(834)	
Prepaid and other assets	(2,084)	(5,200)	(3,133)
Accounts payable	9,968	16,661	13,813
Accrued expenses	68,352	22,958	39,565
Due to Endo Pharma LLC	5,624		
Income taxes receivable/payable	(68,297)	(12,458)	3,677
Net cash provided by operating activities	284,644	170,545	217,444
INVESTING ACTIVITIES:			
Purchase of property and equipment	(10,491)	(8,118)	(11,344)
Proceeds from sale of property and equipment	7	294	
Payment of license termination fee		(3,000)	
Loan made to Vernalis		(50,000)	
License fees	(14,500)	(46,500)	(32,500)
Other investments	(1,700)	(500)	(500)
Net cash used in investing activities	(26,684)	(107,824)	(44,344)
FINANCING ACTIVITIES:			
Capital lease obligations repayments	(2,452)	(1,484)	(583)
Tax sharing payments to Endo Pharma LLC	(42,775)	(13,549)	
Exercise of Endo Pharmaceuticals Holdings Inc. Stock Options and Warrants	10,189	773	154

Net cash used in financing activities	(35,038)	(14,260)	(429)
NET INCREASE IN CASH AND CASH EQUIVALENTS	222,922	48,461	172,671
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	278,034	229,573	56,902
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 500,956	$ 278,034	$ 229,573
SUPPLEMENTAL INFORMATION:			
Interest paid	$ 878	$ 415	$ 378
Income taxes paid	$ 17,002	$ 48,901	$ 84,751
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Purchase of property and equipment financed by capital leases	$ 5,546	$ 5,071	$ 391
Change in accrual for purchases of property and equipment	$ (1,560)	$ (1,527)	$ (815)

See notes to consolidated financial statements.

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ENDO PHARMACEUTICALS HOLDINGS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003

1. Description of Business

Endo Pharmaceuticals Holdings Inc. (the Company or we) is a specialty pharmaceutical company with market leadership in pain management. The Company, through its wholly owned subsidiary, Endo Pharmaceuticals Inc. (Endo or EPI), is engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used to treat and manage pain, primarily in the United States. The Company was incorporated on November 18, 1997 under the laws of the state of Delaware. The stock of Endo is the only asset of the Company, and the Company has no other operations or business.

2. Summary of Significant Accounting Policies

Principles of Consolidation The consolidated financial statements include the accounts of Endo Pharmaceuticals Holdings Inc. and its subsidiaries. All significant intercompany balances and transactions have been eliminated.

Customer, Product and Supplier Concentration We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply products to pharmacies, hospitals, governmental agencies and physicians. We are potentially subject to a concentration of credit risk with respect to our trade receivables. Three distributors and one pharmacy chain individually accounted for 31%, 27%, 13% and 3%, respectively, of our net sales in 2005. Three distributors and one pharmacy chain individually accounted for 29%, 18%, 18% and 9%, respectively, of our net sales in 2004. Three distributors and one pharmacy chain individually accounted for 26%, 26%, 19% and 11%, respectively, of our net sales in 2003. We perform ongoing credit evaluations of our customers and maintain sufficient allowances for estimated uncollectible accounts. Generally, we do not require collateral from our customers. Net sales of Lidoderm®, generic oxycodone extended release, Percocet®, Endocet®, and generic morphine sulfate accounted for: 51%, 14%, 13%, 8% and 5%; 50%, 0%, 14%, 19% and 10%; and 30%, 0%, 36%, 11% and 16% of our net sales for the years ended December 31, 2005, 2004 and 2003, respectively.

We have agreements with Novartis Consumer Health, Inc. and Teikoku Seiyaku Co., Ltd. for the manufacture and supply of a substantial portion of our existing pharmaceutical products (see Note 12). In the event of any interruption in the manufacture and supply of these products due to regulatory or other causes, there can be no assurance that we could make alternative arrangements on a timely basis, if at all. Such interruption could have a material adverse effect on our business, financial condition and results of operations.

Revenue Recognition Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. We recognize revenue for product sales when title and risk of loss has passed to the customer, which is typically upon delivery to the customer, when estimated provisions for chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses are reasonably determinable, and when collectibility is reasonably assured.

Sales Deductions When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. These provisions are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be materially impacted.

The provision for chargebacks is one of the most significant and the most complex estimate used in the recognition of our revenue. We establish contract prices for indirect customers who are supplied by our wholesale customers. A chargeback represents the difference between our invoice price to the wholesaler and the indirect customer s contract price. Provisions for estimating chargebacks are calculated primarily using historical chargeback experience, estimated wholesaler inventory levels and estimated future trends. We also establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives and other allowances. Some customers receive rebates upon attaining established sales volumes. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. We estimate an accrual for Medicaid rebates as a reduction of revenue at the time

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product sales are recorded. The Medicaid rebate reserve is estimated based upon the historical payment experience, historical relationship to revenues and estimated future trends. Medicaid pricing programs involve particularly difficult interpretations of statutes and regulatory guidance, which are complex and thus our estimates could differ from actual experience. Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties, payable to Hind, are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. Royalties are paid to Hind at a rate of 10% of net sales of Lidoderm®. Our return policy allows customers to receive credit for expired products within three to six months prior to expiration and within one year after expiration. We estimate the provision for product returns based upon the historical experience of returns for each product, historical relationship to revenues, estimated future trends, estimated customer inventory levels and other competitive factors. We continually monitor the factors that influence each type of sales deduction and make adjustments as necessary.

Research and Development Expenditures for research and development are expensed as incurred. Property and equipment that are acquired or constructed for research and development activities and that have alternate future uses are capitalized and depreciated over their estimated useful lives on a straight-line basis.

Cash and Cash Equivalents The Company considers all highly liquid investments with an original maturity date of three months or less to be cash equivalents.

Concentrations of Credit Risk Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents, accounts receivable and our note receivable. We invest our excess cash in high-quality, liquid money market instruments maintained by financial institutions. We have not experienced any significant losses on our cash equivalents. We perform ongoing credit evaluations of our customers and generally do not require collateral. Approximately 75% and 71% of our accounts receivable balance represent amounts due from three and four customers at December 31, 2005 and 2004, respectively. Our note receivable is secured by certain assets of the counterparty and future royalty and milestone payments due from the counterparty (See Note 8).

Fair Value of Financial Instruments The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses are a reasonable estimate of their fair values because of the current maturities of these instruments. The carrying amount of our note receivable approximates its fair value as the effective rate for this note is comparable to market rates at December 31, 2005. Marketable securities, which are included in other assets, are comprised of our investment in shares of common stock of DURECT Corporation, are recorded at their fair value of approximately $7.8 million at December 31, 2005.

Inventories Inventories consist of finished goods held for distribution, raw materials and work in process. Our inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results. Inventories also include costs associated with certain products prior to regulatory approval and/or resolution of patent infringement litigation based on management s judgment of probable future commercial use and net realizable value.

Property and Equipment Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the related assets, ranging from two to ten years, on a straight-line basis. Leasehold improvements and capital lease assets are amortized on a straight-line basis over the shorter of their estimated useful lives or the terms of their respective leases and this amortization is included in depreciation expense.

License Rights Licenses are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives ranging from twelve to twenty years, with a weighted average useful life of approximately 16 years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and net income per share to decrease.

Patents Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

Impairment of Long-Lived Assets Long-lived assets, which includes property and equipment, license rights and patents, are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or*

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Disposal of Long-Lived Assets (SFAS No. 144), whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows generated by that asset. In the event the carrying value of the asset exceeds the undiscounted future cash flows generated by that asset and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. As a result of the significance of our long-lived assets, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations.

Goodwill Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is assessed on an annual basis on January 1st of each year for impairment or more frequently if impairment indicators arise. SFAS No. 142, *Goodwill and Other Intangible Assets,* prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit s fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit s goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

Advertising Costs Advertising costs are expensed as incurred and included in selling, general and administrative expenses and amounted to $23.2 million, $30.2 million and $25.5 million for the years ended December 31, 2005, 2004 and 2003, respectively.

Income Taxes The Company accounts for income taxes and the related accounts under the liability method. Deferred tax liabilities and assets are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted rates expected to be in effect during the year in which the basis differences reverse.

Litigation The Company is subject to litigation in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses. Accruals are recorded when the Company determines that a loss related to a litigation matter is both probable and reasonably estimable.

License and Collaboration Agreements The Company enters into license and collaboration agreements with third parties whereby the Company purchases the rights to develop, market, sell and/or distribute the underlying pharmaceutical products. Pursuant to these agreements, we are generally required to make up-front payments, milestone payments contingent upon the achievement of certain pre-determined criteria, royalty payments based on specified sales levels of the underlying products and/or certain other payments. Up-front payments are either expensed immediately as research and development or, capitalized. The determination to capitalize amounts related to licenses is based on management s judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products and/or various other competitive factors. Milestone payments made prior to regulatory approval are generally expensed as incurred and milestone payments made subsequent to regulatory approval are generally capitalized as an intangible asset. Royalty payments are expensed as incurred. Other payments made pursuant to license and collaboration agreements, which are generally related to research and development activities, are expensed as incurred.

Stock-Based Compensation The Company accounts for its stock-based employee compensation plan under the intrinsic value method in accordance with Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. The Company has adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure.* In 2006, the Company will adopt SFAS No. 123 (revised

2004), Share-Based Payment, which requires that the fair value of stock options be recorded in the results of operations.

Pro-forma information regarding net income and earnings per share, as presented below, is required by SFAS No. 123, as amended by SFAS No. 148, and has been determined as if the Company had accounted for its employee stock options under the fair value method of SFAS No. 123 as of its effective date. We estimated the fair value of our stock options, as of the respective date of grant, using a Black-Scholes option-pricing model. The following weighted average assumptions were used for such estimates: no dividend yield; expected volatility of 58% in 2005, 63% in 2004 and 70% in 2003; risk-free interest rate of 3.8%, 3.2% and 3.2% for 2005, 2004 and 2003, respectively; and a weighted average expected life of the options of 5 years. Had the Company elected to adopt the

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fair value recognition provisions of SFAS No. 123, pro forma net income and net income per share would be as follows (in thousands, except per share data):

	Years Ended December 31		
	2005	2004	2003
Net income, as reported	$ 202,295	$ 143,309	$ 69,790
Add: Stock-based employee compensation expense included in reported net income			144,524
Deduct: Tax effect of stock-based employee compensation expense			(55,536)
Deduct: Total stock-based employee compensation expense determined under fair value based methods for all awards	(7,203)	(5,901)	(69,981)
Add: Tax effect of stock-based employee compensation expense under fair value based methods	2,766	2,244	26,891
Pro forma net income	$ 197,858	$ 139,652	$ 115,688
Basic earnings per share, as reported	$ 1.53	$ 1.09	$ 0.54
Basic earnings per share, pro forma	$ 1.50	$ 1.06	$ 0.90
Diluted earnings per share, as reported	$ 1.52	$ 1.08	$ 0.53
Diluted earnings per share, pro forma	$ 1.48	$ 1.05	$ 0.87
Weighted average shares outstanding			
Basic	132,242	131,805	128,417
Diluted	133,289	132,718	132,439

Use of Estimates The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and use assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The most significant estimates made and assumptions used are in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses; inventory reserves; deferred taxes; contingencies; the capitalization of and the selection of amortization periods for intangible assets with finite lives; and the assessment of the recoverability of goodwill and intangible assets.

Segment Information We report segment information in accordance with SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. We have one reportable segment, pharmaceutical products.

Comprehensive Income Comprehensive income includes all changes in equity during a period except those that resulted from investments by or distributions to a company s stockholders. Other comprehensive income refers to revenues, expenses, gains and losses that are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an adjustment to stockholders equity. Our other comprehensive income is comprised of unrealized holding gains and losses, net of income taxes, on the 1.5 million shares of publicly traded common stock of DURECT that we own.

Reclassifications During the year ended December 31, 2005, the Company determined that acquisitions of property and equipment on account, which were previously reported as a component of changes in operating assets and liabilities and purchases of property and equipment, are now more appropriately shown as a non-cash investing activity, as opposed to cash used in investing activities, until paid by the Company. Accordingly, the Company s financial statements for the years ended December 31, 2004 and 2003 have now been revised to reflect a decrease in cash provided by operating activities with a corresponding decrease in cash used in investing activities of approximately $1.5 million and $0.8

million, respectively. Purchases of property and equipment acquired on account have now been presented as a supplemental disclosure of non-cash items. This revision has no effect on net income or the amount of cash and cash equivalents reported. Certain other prior period amounts, within the statements of operations, have been reclassified to conform to current year presentation.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4.* The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS No. 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of so abnormal. In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provision of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 is not expected to have a material impact on the Company s results of operations or financial position.

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In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29.* SFAS No. 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005, with earlier application permitted. The adoption of SFAS No. 153 is not expected to have a material impact on the Company s results of operations or financial position.

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payments (revised 2004)*. This statement eliminates the option to apply the intrinsic value measurement provisions of APB Board Opinion No. 25, *Accounting for Stock Issued to Employees*, to stock compensation awards issued to employees. Rather, the Statement requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award the requisite service period (usually the vesting period). In March 2005, the SEC staff expressed their views with respect to SFAS No. 123R in Staff Accounting Bulletin No. 107, *Share-Based Payment*, (SAB 107). SAB 107 provides guidance on valuing options. SFAS No. 123R will be effective for the Company s fiscal year beginning January 1, 2006. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

In March 2005, the FASB issued FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations*, (FIN 47). FIN 47 is an interpretation of SFAS No. 143, *Asset Retirement Obligations*, which was issued in June 2001. FIN 47 was issued to address diverse accounting practices that have developed with regard to the timing of liability recognition for legal obligations associated with the retirement of a tangible long-lived asset in which the timing and/or method of settlement are conditional on a future event that may or may not be within the control of the entity. According to FIN 47, uncertainty about the timing and/or method of settlement of a conditional asset retirement obligation should be factored into the measurement of the liability when sufficient information exists. FIN 47 also clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 was adopted on December 31, 2005 by the Company and its adoption had no impact on our financial statements.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections,* a replacement of APB Opinion No. 20 and Statement No. 3. SFAS 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on the Company s results of operations or financial position.

3. Acquisitions

BML Pharmaceuticals

On July 26, 2002, our wholly owned subsidiary, Endo, acquired BML Pharmaceuticals, Inc. (BML), a privately held company, for an up-front payment of $14 million. In addition, had BML s lead pipeline product, an oral rinse (0.1% triclosan) for oral mucositis, received FDA approval, Endo would have paid the former shareholders of BML a $32 million payment and an earn-out based on a percentage of net sales of certain products in BML s pipeline. BML operates as a wholly owned subsidiary of Endo Pharmaceuticals Inc. We accounted for the acquisition using the purchase method of accounting. In accordance with the purchase method of accounting, the purchase price was allocated to BML s assets and liabilities based on their respective fair values on the date of the acquisition.

The BML acquisition included an on-going project to research and develop an oral rinse product (0.1% triclosan) for oral mucositis. As a result, the allocation of the fair value of the assets acquired and liabilities assumed included an allocation to purchased in-process research and

development (IPRD) of $20.3 million which was expensed in the consolidated statement of operations on the acquisition date. The methodology we used on the acquisition date in determining the value of IPRD was to: 1) identify the various on-going projects that we have determined to prioritize and continue; 2) project net future cash flows of the identified projects based on then current demand and pricing assumptions, less the anticipated expenses to complete the development program, drug application, and launch of the products (significant net cash inflows from the oral rinse product (0.1% triclosan) for oral mucositis were projected in 2004); and 3) discount these cash flows based on a risk-adjusted discount rate of 20%. The discount rate was determined after considering various uncertainties at the time of the acquisition, including the relative risk of the investment and the

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time value of money. The assets acquired and liabilities assumed, results of operations and cash flows of BML have been included in our financial statements prospectively for reporting periods beginning July 26, 2002.

We allocated fair value to one project of BML Pharmaceuticals, an oral rinse (0.1% triclosan) for oral mucositis. The development program for a new pharmaceutical substance involves several different phases prior to drug application. Further, drug applications must be approved by the FDA prior to marketing a new drug. Despite our commitment to completion of this research and development project, many factors may arise that could cause the project to be withdrawn or delayed, including the inability to prove the safety and efficacy of the drug during the development process. Upon withdrawal of an application, it is unlikely that the development activities will have alternative use.

On October 24, 2003, we announced that our pivotal Phase III clinical trial of the oral rinse product did not meet its primary endpoint of preventing oral mucositis. During the fourth quarter of 2003, we made the decision to discontinue our development program for the oral rinse product for the treatment of oral mucositis. As a result, we extinguished the contingent liability related to the program resulting in a gain of $7.0 million in 2003.

4. License and Collaboration Agreements

Penwest Pharmaceuticals

In September 1997, we entered into a collaboration agreement with Penwest Pharmaceuticals to exclusively co-develop opioid analgesic products for pain management, using Penwest s patent-protected proprietary technology, for commercial sale worldwide. On April 2, 2002, we amended and restated this agreement to provide, among other things, that this collaboration would cover only that opioid analgesic product currently under development by the parties, namely, oxymorphone ER. We had historically shared, on an equal basis, the costs of products developed under this agreement. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we have been and continue to be responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup, from the royalties due to Penwest, the full amount of what Penwest should have contributed had it not exercised such right. Penwest is entitled to receive royalties equal to a percentage beginning at 50%, which could decline to 40% based upon the achievement of certain criteria, of the net realization (as defined in the agreement) of oxymorphone ER. We have exclusive U.S. marketing rights with respect to oxymorphone ER, subject to the terms and conditions contained in this agreement.

Hind Healthcare Inc.

In November 1998, Endo entered into a license agreement (the Hind License Agreement) with Hind Healthcare Inc. (Hind) for the sole and exclusive right to develop, use, market, promote and sell Lidoderm® in the United States. Under the terms of the Hind License Agreement, Endo paid Hind approximately $10 million (the Hind License Fee) based upon the achievement of certain milestones and capitalized this amount as an intangible asset representing the fair value of these exclusive rights. In addition, Endo pays Hind nonrefundable royalties based on net sales of the product. Royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least $500,000 per year. During 2005, 2004 and 2003, we accrued $46.4 million, $34.5 million and $19.9 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales. In March 2002, we extended this license with Hind to cover Lidoderm® in Canada and Mexico.

Lavipharm Laboratories, Inc.

In November 1999, Endo entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which Endo obtained exclusive worldwide rights to Lavipharm s existing drug delivery technology platforms. Under the terms of this collaboration agreement, Endo paid an upfront license fee of $1 million. In September 2001, we amended this agreement to limit its scope to one of Lavipharm s existing drug delivery technologies in combination with two specific active drug substances. In January 2004, we terminated this agreement and made a termination payment to Lavipharm of $3 million plus the potential for up to an additional $5 million in contingent termination payments upon the occurrence of future events. The payment of this additional contingent termination amounts is not likely due the fact that U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven s Abbreviated New Drug Application for its developmental transdermal fentanyl patch, as discussed

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below. We wrote-off the unamortized portion of the upfront license fee and expensed the termination payment of $3 million during the year ended December 31, 2004.

DURECT Corporation

In November 2002, Endo entered into a license agreement (DURECT CHRONOGESIC License Agreement) with DURECT Corporation (DURECT) to develop and commercialize DURECT s CHRONOGESIC (sufentanil) Pain Therapy System for the U.S. and Canada. In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Prior to this amendment, in addition to other specified termination rights provided to both parties, the Agreement provided Endo with a right to terminate the Agreement starting January 1, 2006 in the event that DURECT had not commenced a specified clinical trial for the CHRONOGESIC™ product candidate on or before January 1, 2006, *provided that* Endo provided DURECT written notice of such termination prior to January 31, 2006. Under Amendment No. 3, the foregoing termination right was amended to provide Endo with the right to terminate the Agreement in the event that (i) DURECT had not delivered to Endo on or before March 31, 2007 a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC™ product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT s delivery of the Notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2007. Under Amendment No. 3, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2007. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product candidate in accordance with the terms of the Agreement. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT CHRONOGESIC License Agreement could total up to $52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC . In addition, the DURECT CHRONOGESIC License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT CHRONOGESIC License Agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, the DURECT CHRONOGESIC License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT up to $10.0 million. Finally, in connection with this agreement, on November 8, 2002, Endo purchased approximately 1.5 million common shares of DURECT.

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a $10 million upfront fee that has been expensed as research and development in year ended December 31, 2005, with additional payments of approximately $35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

SkyePharma, Inc.

In December 2002, we entered into a Development and Marketing Strategic Alliance Agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. relating to two of SkyePharma s patented development products, DepoDur® and Propofol IDD-D (collectively, the Skye Products). Under the terms of the Agreement, Endo received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other development products. In return, Endo made a $25 million upfront payment to SkyePharma, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We were

amortizing this intangible asset over its useful life of 17 years. During the year ended December 31, 2005, we recorded a receivable from SkyePharma of $5 million based upon the achievement of certain criteria as specified in the agreement. This receivable has been recorded as a reduction to our recorded intangible asset and the intangible asset is now being amortized over its remaining useful life of 15 years. We collected this receivable in January 2006. In addition, SkyePharma may receive additional contingent milestone payments of up to $95 million ($15 million of which has been paid as of December 31, 2005). During the year ended December 31, 2003, we paid and expensed to research and development a $5 million

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milestone payment to SkyePharma upon the acceptance by the FDA of the NDA for DepoDur®. During the year ended December 31, 2004, we paid and expensed to research and development a $5 million milestone payment to SkyePharma upon approval of the NDA for DepoDur®. The additional contingent milestone payments also include up to $50 million ($5 million of which has been paid as of December 31, 2005) for Propofol IDD-D , payable when the product successfully achieves certain regulatory milestones, including FDA approval. During the year ended December 31, 2004, we paid and expensed to research and development a $5 million milestone payment to SkyePharma upon the advancement of Propofol IDD-D to the end of Phase II clinical development. The total further includes a $15 million milestone payable when net sales of DepoDur® exceed $125 million in a calendar year, and a $20 million milestone payable when net sales of DepoDur® exceed $175 million in a calendar year. SkyePharma will also receive a share of each product s sales revenue that will increase from 20% initially, to a maximum of 60%, of net sales as the Skye Products combined net sales achieve certain thresholds. This agreement provides for the parties to work together to complete the necessary clinical, regulatory and manufacturing work for North American regulatory approval of the Skye Products. SkyePharma will be primarily responsible for clinical development up to final FDA approval, and for the manufacture of the Skye Products, including all associated costs. Upon approval, we will market each Skye Product in the U.S. and Canada, with SkyePharma as the supplier. We are responsible for funding and conducting any post-marketing studies and for all selling and marketing expenses. Under this agreement, we also obtained options on other SkyePharma development products, including DepoBupivicaine , a long-acting, sustained release formulation of the local anesthetic bupivacaine. We had the option to obtain commercialization rights for this product when SkyePharma successfully completes its Phase II trials; however, in February 2006 we relinquished our rights to DepoBupivicaine . In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require us to pay SkyePharma $5.0 million.

Noven Pharmaceuticals, Inc.

In February 2004, we entered into a License Agreement and a Supply Agreement with Noven Pharmaceuticals, Inc. under which Noven exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson s Duragesic® (fentanyl transdermal system). We made an upfront payment of $8.0 million, $1.5 million of which we expensed as research and development costs and $6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We were amortizing this intangible asset over its useful life of 11 years. On September 27, 2005, the U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven s Abbreviated New Drug Application for its developmental transdermal fentanyl patch based on the FDA s assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic®. As a result, we incurred a charge of approximately $4 million related to the write-off of our portion of the transdermal fentanyl patch inventory and an impairment charge of approximately $5.5 million, which represents the unamortized portion of the upfront license fee that we paid Noven in February 2004, during the year ended December 31, 2005. On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

EpiCept Corp.

In December 2003, we entered into a license granting us exclusive, worldwide rights to certain patents of EpiCept Corp. as well as exclusive, worldwide commercialization rights to EpiCept s LidoPAIN® BP product. The license agreement provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept s LidoPAIN® BP product. Under this agreement, we made an upfront payment to EpiCept of $7.5 million which we capitalized as an intangible asset representing the fair value of the exclusive right and the patents. We are amortizing this intangible asset over its useful life of 13 years. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Milestone payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to $82.5 million. In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents expire.

Vernalis Development Limited

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova® is indicated for the acute treatment of migraine headaches in adults. Under the terms of the license agreement, we

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paid Vernalis an upfront fee of $30 million and are required to make anniversary payments for the first two years at $15 million in 2005 and 2006 (the first $15 million anniversary payment was made in 2005), and a $40 million milestone payment upon U.S. Food and Drug Administration, FDA, approval for the menstrual migraine indication (MM). We have capitalized the $30 million up-front payment, the present value of the two $15 million anniversary payments and the difference of $6.2 million between the face amount of the note and its present value at inception (See Note 8) as an intangible asset representing the fair value of the exclusive license to market Frova®. We are amortizing this intangible asset over its estimated useful life of 15 years. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of $10 million on $200 million in net sales to a milestone of $75 million on $1.2 billion in net sales. These sales milestones could total up to $255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova®. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova® or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova® is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years written notice.

On July 1, 2005, we entered into a co-promotion Agreement, as amended on December 22, 2005, with Vernalis. The co-promotion agreement, as amended, is related to that certain license agreement that we entered into on July 14, 2004 with Vernalis, under which Vernalis agreed to exclusively license to us rights to market the product Frova® (frovatriptan) in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova® in the United States. Vernalis has exercised its co-promotion option, and the co-promotion agreement, as amended, sets forth the certain specific terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the license agreement. Under the terms of both the license and co-promotion agreements, both as amended, we will reimburse Vernalis for certain defined costs of their sales personnel beginning in January 2006.

Orexo AB

In August 2004, we entered into an agreement granting us the exclusive rights to develop and market Orexo AB s (a Swedish company) patented sublingual muco-adhesive fentanyl product (Rapinyl) in North America. Rapinyl is a sub-lingual, fast-dissolving tablet of fentanyl intended for the treatment of breakthrough cancer pain. Rapinyl is based on Orexo s unique patented technology for sublingual administration. The agreement provided for us to make an up-front license fee payment of $10 million, which we capitalized as an intangible asset representing the fair value of the exclusive right to market the product and are amortizing over its estimated useful life of 20 years, in addition to other license fees and payments based on development and regulatory milestones, which may total up to $22.1 million ($7.3 million of which was recorded during the year ended December 31, 2005 and included in research and development expense) through FDA approval of Rapinyl s New Drug Application. The Company expects to pay an additional $5.2 million in 2006. The agreement also provides for royalties upon commercial sales and may include sales milestones if defined sales thresholds are achieved. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the expiration of any market exclusivity right. We can terminate the license agreement under certain circumstances, including upon six months written notice, and we may be required to pay a termination fee of up to $750,000.

ProEthic Pharmaceuticals, Inc.

On March 14, 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, in March 2005, we paid a $10 million upfront fee that has been expensed as research and development during the year ended December 31, 2005, and we could be required to make additional payments of approximately $13.0 million upon the achievement of certain regulatory and other milestones. We will

also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the tenth (10th) anniversary of the date of the first commercial sale of the product. We can terminate the agreement at any time upon no more than ninety (90) days written notice.

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ZARS Pharma.

On January 6, 2006, we entered into an agreement with ZARS Pharma for the North American rights to Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical patch. Synera™ is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the U.S. Food and Drug Administration on June 23, 2005, Synera™ is expected to become commercially available in the second half of 2006.

Under the terms of the agreement, we paid ZARS an upfront fee of $11 million which has been capitalized in January 2006 and may be required to make additional payments of up to approximately $27 million upon achievement of certain commercial milestones, $8 million of which will be due upon the first commercial sale of the product, which is expected in the second half of 2006. We will also pay ZARS royalties on net sales of Synera™.

Other

We have licensed from universities and other companies rights to certain technologies or intellectual property generally in the field of pain management. We are generally required to make upfront payments as well as other payments upon successful completion of regulatory or sales milestones. In addition, these agreements generally require us to pay royalties on sales of the products arising from these agreements. These agreements generally permit Endo to terminate the agreement with no significant continuing obligation.

5. Inventories, net

Inventories are comprised of the following at December 31, 2005 and 2004, respectively (in thousands):

	2005	2004
Raw Materials	$ 13,094	$ 14,936
Work-in-Process	7,868	16,294
Finished Goods	30,021	40,185
Total	$ 50,983	$ 71,415

6. Property and Equipment

Property and equipment is comprised of the following at December 31, 2005 and 2004, respectively (in thousands):

	2005	2004
Machinery and equipment	$ 6,278	$ 5,322
Leasehold improvements	13,500	10,285
Computer equipment and software	12,726	9,905
Assets under capital leases	10,506	6,648
Furniture and fixtures	5,527	3,777
Construction in progress	9,196	7,029
	57,733	42,966
Less accumulated depreciation	(19,732)	(14,091)
Total	$ 38,001	$ 28,875

Depreciation expense was $7.8 million, $5.5 million and $4.1 million for the years ending December 31, 2005, 2004 and 2003, respectively.

7. Goodwill and Other Intangibles

Goodwill and other intangible assets consist of the following at December 31, 2005 and 2004, respectively (in thousands):

	2005	2004
Goodwill	$ 181,079	$ 181,079
Amortizable Intangibles:		
Licenses	$ 112,100	$ 123,600
Patents	3,200	3,200
	115,300	126,800
Less accumulated amortization	(16,235)	(9,542)
Other Intangibles, net	$ 99,065	$ 117,258

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Goodwill and other intangibles represent a significant portion of our assets and stockholders equity. As of December 31, 2005, goodwill and other intangibles comprised approximately 20% of our total assets and 33% of our stockholders equity. SFAS No. 142, Goodwill and Other Intangible Assets, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit s fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit s goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. On January 1, 2006, 2005 and 2004, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from twelve to twenty years, with a weighted average useful life of approximately 16 years. The determination to capitalize amounts related to licenses is based on management s judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products and/or various other competitive factors. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty. During the year ended December 31, 2005, the Company expensed $20 million with respect to the acquisitions of marketing and development license rights for two products that are currently in development. We expensed the cost of these license rights based on the fact that we acquired both marketing and development rights for products that do not have regulatory approval and that do not have currently identifiable alternative future uses. As such, it was determined that the cost of the right to develop the products and the cost of the right to market the products were inextricably linked and therefore expensed in the accompanying financial statements. Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

Amortization expense was $7.7 million, $5.1 million and $2.2 million for the years ending December 31, 2005, 2004 and 2003, respectively. As of December 31, 2005, estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2005 is as follows (in thousands):

2006	$ 7,235
2007	7,235
2008	7,235
2009	7,235
2010	7,235

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8. Note Receivable

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova® (frovatriptan) in North America. Under the loan agreement, we provided Vernalis with a loan of $50 million in August 2004. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis reacquisition of the North American rights to Frova®. The loan is secured against the revenues receivable by Vernalis under the license agreement. At our election, we are able to offset $20 million of the $40 million menstrual migraine indication approval milestone and 50% of all royalties to be paid under the license agreement to Vernalis to repay the loan. To the extent not previously repaid, the loan is due in full after five years. Interest is at the rate of 5% per annum payable semi-annually. However, Vernalis has the option to defer payment of interest and increase the loan outstanding each time an interest payment becomes due. In January and July 2005, Vernalis elected to defer payment of the semi-annual interest amounts otherwise due January 31 and July 31, 2005 totaling approximately $2.4 million. In January 2006, Vernalis elected to defer payment of the semi-annual interest payment otherwise due January 31, 2006 totaling an additional $1.3 million

We estimated that an approximate fair market rate of interest for this type of secured loan was 8% per annum and therefore recorded the note receivable at its present value at inception of $43.8 million. The note receivable is being accreted up to its face amount at maturity using the effective interest method and thus the effective interest rate over the five year term will be 8% per annum. The difference of $6.2 million between the face amount of the note and its present value at inception has been treated as additional consideration paid to acquire the license rights and has been included in Other Intangibles. Interest income recognized on this note receivable was $3.9 million and $1.2 million for the years ended December 31, 2005 and 2004, respectively.

9. Accrued Expenses

Accrued expenses are comprised of the following at December 31, 2005 and 2004, respectively (in thousands):

	2005	2004
Chargebacks	$ 50,808	$ 40,290
Returns	21,215	21,649
Rebates	95,565	50,773
Other sales deductions	15,338	4,450
License fees	14,633	14,667
Other	16,717	13,385
Total	$ 214,276	$ 145,214

10. Credit Facility

In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of $75.0 million. The line of credit expires on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. On April 30, 2004, we

amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. As of December 31, 2005, we have not borrowed under the credit facility.

Borrowings under the Amended and Restated Credit Agreement bear interest, which is payable at least quarterly, at a rate equal to the bank s floating alternate base rate plus a premium ranging from 0.75% to 1.25%, or at a rate equal to LIBOR plus a premium ranging from 1.75% to 2.25%, depending on the type of borrowing and our performance against certain criteria.

Additionally, fees are charged on the average daily unused amount of the Amended and Restated Credit Agreement at a rate ranging from 0.375% to 0.50% depending on our performance against certain criteria. This commitment fee is payable quarterly.

The Amended and Restated Credit Agreement contains limitations and restrictions concerning, among other things, additional indebtedness, acquisition or disposition of assets, dividend payments and transactions with affiliates. In addition, the Amended and Restated Credit Agreement requires us to maintain certain ratios (as defined therein).

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11. Income Taxes

Income tax consists of the following for 2005, 2004, and 2003 (in thousands):

	2005	2004	2003
Current:			
Federal	$ (53,318)	$ 32,189	$ 80,119
State	29	5,404	12,863
	(53,289)	37,593	92,982
Deferred:			
Federal	156,468	43,912	(50,828)
State	18,674	6,300	(8,442)
	175,142	50,212	(59,270)
Valuation allowance	96	(18)	5,496
Total income tax	$ 121,949	$ 87,787	$ 39,208

A reconciliation of income tax at the federal statutory income tax rate to the total income tax provision for 2005, 2004, and 2003 is as follows (in thousands) Certain prior year amounts have been reclassified to conform to the current year presentation:

	2005	2004	2003
Federal income tax at the statutory rate	$ 113,485	$ 80,884	$ 38,150
State income tax net of federal benefit	12,157	7,511	3,261
Research and development credit	(1,686)	(588)	(1,400)
Effect of permanent items:			
Purchased in-process research and development			(2,438)
Tax exempt interest income	(1,937)	(345)	
Other	(70)	325	1,635
Total income tax	$ 121,949	$ 87,787	$ 39,208

The tax effects of temporary differences that comprise the current and non-current deferred income tax amounts shown on the balance sheets at December 31 are as follows (in thousands):

	2005	2004

Deferred tax assets:		
Accrued expenses	$ 70,146	$ 47,481
Compensation related to stock options		39,832
Purchased in-process research and development	7,722	8,895
Net operating loss carryforward	4,870	
Capital loss carryforward	5,574	5,478
Other intangible assets	5,429	
Other	698	1,029
Total gross deferred income tax assets	94,439	102,715
Deferred tax liabilities:		
Depreciation and amortization	(31,700)	(30,743)
Other	(2,088)	(936)
Total gross deferred income tax liabilities	(33,788)	(31,679)
Valuation allowance	(5,574)	(5,478)
Net deferred income tax asset	$ 55,077	$ 65,558

As a result of the significant tax deductions generated in 2005 from the exercise of stock options, we have incurred a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of a portion of prior years payments during 2006. As a result, we have recorded an income tax receivable at December 31, 2005.

The estimated fair value of the BML purchased in-process research development of $20.3 million was not a tax deductible item and, therefore, increased our effective income tax rate in 2002 and the reversal of $7.0 million in 2003 decreased our effective income tax rate in 2003. The Company recorded a valuation allowance in 2003 due to the uncertainty of its ability to utilize the capital losses that arose with the write off of the BML investment. At December 31, 2005, the Company had $14.6 million in capital loss

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carryforwards, for tax purposes, which expire in 2009. Also, at December 31, 2005, the Company had $149.8 million in state net operating loss carryforwards which expire at various intervals between 2010 and 2025.

12. Commitments and Contingencies

Manufacturing, Supply and Other Service Agreements We contract with various third party manufacturers and suppliers to provide us with our raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Teikoku Seiyaku Pharmaceuticals and Mallinckrodt. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, this may have a material adverse effect on our business, financial condition and results of operations.

Novartis Consumer Health, Inc.

On May 3, 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc. whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. As of December 31, 2005, we are required to purchase a minimum of $7.8 million per year through December 31, 2009. Amounts paid pursuant to this agreement were $39.9 million, $27.7 million and $29.7 million for the years ended December 31, 2005, 2004 and 2003, respectively. Either party may terminate this agreement on three-years notice, effective at any time after the initial five-year term. In addition, we may terminate this agreement effective prior to the fifth anniversary of the agreement upon three-years notice and the payment of certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

Teikoku Seiyaku Co., Ltd.

Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. The purchase price for the product is equal to a predetermined amount per unit of product. We are required to purchase a minimum of approximately $18 million of product from Teikoku in 2006. Amounts paid pursuant to this agreement were $89.8 million, $94.2 million and $38.6 million for the years ended December 31, 2005, 2004 and 2003, respectively. The term of this agreement is from November 23, 1998 until the shorter of (1) the expiration of the last to expire patent that is licensed to us from Hind Healthcare Inc. or (2) November 20, 2011. This agreement may be terminated for material breach by either party and by us if the Hind Healthcare license agreement is terminated.

Mallinckrodt Inc.

Under the terms of this agreement, Mallinckrodt manufactures and supplies to us narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. We are required to purchase a fixed percentage of our annual requirements of each narcotic active drug substance from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party may terminate this agreement for a material breach.

In addition, under a separate agreement, Mallinckrodt exclusively manufactures and supplies to us a narcotic active drug substance that is not covered under the previously discussed Mallinckrodt agreement. We are required to purchase a fixed percentage of our annual requirements of this narcotic active drug substance from Mallinckrodt. The purchase price of the substance is a fixed amount that may be adjusted annually in the event of Mallinckrodt product cost increases. The current term of this agreement is April 1, 1998 until June 30, 2004, as extended pursuant to an amendment, dated as of May 8, 2000, with an automatic renewal provision for unlimited successive one-year periods, unless terminated by either party. The current renewal term expires on June 30, 2006. This agreement may also be terminated for material breach by either party. Amounts paid pursuant to these agreements were $24.6 million, $18.9 million and $33.2 million for the years ended December 31, 2005, 2004 and 2003, respectively.

General

In addition to the manufacturing and supply agreements described above, we have agreements with (1) UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and

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certain financial functions that expires in 2010, (2) Kunitz and Associates Inc. for assistance with adverse event reporting and (3) PPD Development, LP for clinical development services, business development support and medical information services. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition and/or results of operations.

License Agreements, Milestones and Royalties

Hind Healthcare Inc.

Under the terms of the Hind License Agreement, royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. The royalty rate is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least $500,000 per year. During the years ended December 31, 2005, 2004 and 2003, we accrued $46.4 million, $34.5 million and $19.9 million for these royalties to Hind, respectively.

Penwest Pharmaceuticals

Under the terms of the amended and restated strategic alliance agreement with Penwest Pharmaceuticals Co. (Penwest), Penwest is entitled to receive royalties equal to a percentage beginning at 50%, which could decline to 40% based upon the achievement of certain criteria, of the net realization (as defined in the agreement) of oxymorphone ER. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of this product on account of their concern about their ability to access external capital funding opportunities in the future. Accordingly, we have been and continue to be responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup, from the royalties due to Penwest, the full amount of what Penwest should have contributed had it not exercised such right.

Lavipharm Laboratories, Inc.

In November 1999, Endo entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which Endo obtained exclusive worldwide rights to Lavipharm s existing drug delivery technology platforms. Under the terms of this collaboration agreement, Endo paid an upfront license fee of $1 million. In September 2001, we amended this agreement to limit its scope to one of Lavipharm s existing drug delivery technologies in combination with two specific active drug substances. In January 2004, we terminated this agreement and made a termination payment to Lavipharm of $3 million plus the potential for up to an additional $5 million in contingent termination payments upon the occurrence of future events. The payment of this additional contingent termination amounts is not likely due the fact that U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven s Abbreviated New Drug Application for its developmental transdermal fentanyl patch, as discussed below. We wrote-off the unamortized portion of the upfront license fee and expensed the termination payment of $3 million during the year ended December 31, 2004.

DURECT Corporation

In January 2006, DURECT and Endo entered into Amendment No. 3 to the DURECT CHRONOGESIC License Agreement. Prior to this amendment, in addition to other specified termination rights provided to both parties, the Agreement provided Endo with a right to terminate the Agreement starting January 1, 2006 in the event that DURECT had not commenced a specified clinical trial for the CHRONOGESIC™ product candidate on or before January 1, 2006, *provided that* Endo provided DURECT written notice of such termination prior to January 31, 2006. Under Amendment No. 3, the foregoing termination right was amended to provide Endo with the right to terminate the Agreement in the event that (i) DURECT had not delivered to Endo on or before March 31, 2007 a written notice that a human pharmacokinetic trial had been completed with the CHRONOGESIC™ product candidate, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT s delivery of the Notice, *provided that*, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2007. Under Amendment No. 3, Endo shall not be responsible for any development costs for the CHRONOGESIC™ product candidate prior to May 1, 2007. Commencing on May 1, 2007, unless the Agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs for the CHRONOGESIC™ product candidate in accordance with the terms of the Agreement. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the DURECT CHRONOGESIC License Agreement could total up to $52.0 million. Endo and DURECT will share profits equally, based on projected financial performance of

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CHRONOGESIC . In addition, the DURECT CHRONOGESIC License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT CHRONOGESIC License Agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, the DURECT CHRONOGESIC License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT up to $10.0 million.

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT s sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a $10 million upfront fee, which was expensed as research and development in the first quarter of 2005, with additional payments of approximately $35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

SkyePharma, Inc.

Under the terms of our agreement with SkyePharma, we are required to pay to SkyePharma a share of each product s sales revenue, which share may increase from 20% initially, to a maximum of 60%, of net sales as the products combined sales achieve certain thresholds. In addition, future milestone payments may be due SkyePharma as follows (in thousands):

Milestone Event	Milestone Payment
The first time net sales of DepoDur® in a calendar year exceed $125,000	$ 15,000
The first time net sales of DepoDur® in a calendar year exceed $175,000	20,000
Total contingent sales milestones for DepoDur®	$ 35,000
FDA acceptance of the NDA for Propofol IDD-D in the United States	5,000
FDA final approval of the NDA for Propofol IDD-D in the United States	40,000
Total contingent regulatory milestones for Propofol IDD-D	$ 45,000

In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require us to pay SkyePharma $5.0 million.

Noven Pharmaceuticals, Inc.

Under the terms of our license agreement with Noven, upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. The profit on the product will be shared. This license agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven s transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

On September 27, 2005, the U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven s Abbreviated New Drug Application for its developmental transdermal fentanyl patch based on the FDA s assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic®. As a result, we incurred a charge of approximately $4 million related to the write-off of our portion of the transdermal

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fentanyl patch inventory and an impairment charge of approximately $5.5 million, which represents the unamortized portion of the upfront license fee that we paid Noven in February 2004. On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

EpiCept Corp.

Our license agreement with EpiCept provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept s LidoPAIN® BP product. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Under this agreement, Endo also received an exclusive, worldwide license to certain patents of EpiCept Corp. Milestone payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to $82.5 million.

Vernalis Development Limited

Under the terms of our license agreement with Vernalis, we will make anniversary payments for the first two years of $15 million in 2005 and 2006 (the first $15 million anniversary payment was made in September 2005), and a $40 million milestone payment upon FDA approval for the menstrual migraine indication. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of $10 million on $200 million in net sales to a milestone of $75 million on $1.2 billion in net sales. These sales milestones could total up to $255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova®. On July 1, 2005, we entered into a co-promotion Agreement, as amended on December 22, 2005, with Vernalis. The co-promotion agreement, as amended, is related to that certain license agreement that we entered into on July 14, 2004 with Vernalis, under which Vernalis agreed to exclusively license to us rights to market the product Frova® (frovatriptan) in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova® in the United States. Vernalis has exercised its co-promotion option, and the co-promotion agreement, as amended, sets forth the certain specific terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the license agreement. Under the terms of both the license and co-promotion agreements, both as amended, we will reimburse Vernalis for certain defined costs of their sales personnel beginning in January 2006.

Orexo AB

Our agreement with Orexo provides for us to make additional license fees and payments based on development and regulatory milestones, which may total up to $22.1 million through FDA approval of Rapinyl s New Drug Application, $7.3 million of which was recorded during the year ended December 31, 2005 and has been included in research and development expense. The Company expects to pay an additional $5.2 million in 2006. The agreement also provides for royalties upon commercial sales and may include sales milestones, up to $39.2 million, if defined sales thresholds are achieved. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the expiration of any market exclusivity right. We can terminate the license agreement under certain circumstances, including upon six months written notice, and we may be required to pay a termination fee of up to $750,000.

ProEthic Pharmaceuticals, Inc.

On March 14, 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic s European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, in March 2005, we made a $10 million upfront payment, which was expensed as research and development during the year ended December 31, 2005, and we could be required to make additional payments of approximately $13.0 million for the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of this license agreement shall be until the later of (i) the expiration of the patents or

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(ii) the tenth (10th) anniversary of the date of the first commercial sale of the product. We can terminate the agreement at any time upon no more than ninety (90) days written notice.

Zars Pharma.

On January 6, 2006, we entered into an agreement with ZARS Pharma for the North American rights to Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical patch. Synera™ is for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the U.S. Food and Drug Administration on June 23, 2005, Synera™ is expected to become commercially available in the second half of 2006. Under the terms of the agreement, we paid ZARS an upfront fee of $11 million which has been capitalized in January 2006 and may be required to make additional payments of up to approximately $27 million upon achievement of certain commercial milestones, $8 million of which will be due upon the first commercial sale of the product, which is expected in the second half of 2006. We will also pay ZARS royalties on net sales of Synera™.

Life Sciences Opportunities Fund (Institutional) II, L.P.

On December 12, 2003, we entered into a subscription agreement to invest up to $10 million into Life Sciences Opportunities Fund (Institutional) II, L.P., a Delaware limited partnership formed to carry out investments in life science companies. As part of this investment, we are able to capitalize on the knowledge of LOF Partners, LLC, the general partner, and its access to, life sciences entities with promising pharmaceutical assets, technologies and management talent and on the general partner s wide range of industry contacts and resources. As of December 31, 2005, we have invested $2.7 million in this partnership and are accounting for this investment utilizing the equity method.

Employment Agreements

We have entered into employment agreements with certain members of management.

Research Contracts

In addition to our agreement with PPD Development, LP, we routinely contract with universities, medical centers, contract research organizations and other institutions for the conduct of research and clinical studies on our behalf. These agreements are generally for the duration of the contracted study and contain provisions that allow us to terminate prior to completion.

Collaboration Agreements

We have also entered into certain collaboration agreements with third parties for the development of pain management products. Potential milestone payments pursuant to these contracts could total up to $62 million. These agreements require us to share in the development costs of

such products and grant marketing rights to us for such products. If our third party partners are unable or unwilling to fund their portion of the collaboration project with us, this may adversely affect our results of operations and cash flows in the foreseeable future.

Legal Proceedings

While we cannot predict the outcome of the following legal proceedings, we believe that the claims against us are without merit, and we intend to vigorously defend our position. An adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position and results of operations. No amounts have been accrued with respect to any of these unsettled legal proceedings at December 31, 2005.

Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 00 Civ. 8029 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 2109 (SHS) (S.D.N.Y.); Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 8177 (SHS) (S.D.N.Y.)

On October 20, 2000, The Purdue Frederick Company and related companies (Purdue Frederick) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc. (EPI), in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent version of Purdue Frederick s OxyContin® (oxycodone hydrochloride extended-release tablets), 40mg strength, infringes three of its patents. This suit arose after EPI provided the plaintiffs with notice that its ANDA submission for a bioequivalent version of Purdue Frederick s OxyContin®, 40mg strength, challenged the listed patents for OxyContin® 40mg tablets. On March 13, 2001,

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Purdue Frederick filed a second suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent versions of Purdue Frederick s OxyContin®, 10mg and 20mg strengths, infringe the same three patents. This suit arose from EPI having amended its earlier ANDA on February 9, 2001 to add bioequivalent versions of the 10mg and 20mg strengths of OxyContin®. On August 30, 2001, Purdue Frederick filed a third suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI s bioequivalent version of Purdue Frederick s OxyContin®, 80mg strength, infringes the same three patents. This suit arose from EPI having amended its earlier ANDA on July 30, 2001 to add the bioequivalent version of the 80mg strength of OxyContin®.

For each of the 10mg, 20mg, 40mg and 80mg strengths of this product, EPI made the required Paragraph IV certification against the patents listed in the FDA s Orange Book as covering these strengths of OxyContin®. EPI pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI s formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI also counterclaimed for antitrust damages based on allegations that Purdue Frederick obtained the patents through fraud on the United States Patent and Trademark Office and is asserting them while aware of their invalidity and unenforceability.

The trial of the patent claims in all three of the suits against us and EPI concluded on June 23, 2003. On January 5, 2004, the district court issued an opinion and order holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to inequitable conduct. The district court, therefore, dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the district court s infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo s favor by the U.S. District Court for the Southern District of New York on January 5, 2004. This affirmance by the Federal Circuit Court dismisses the claims that Endo s oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick s OxyContin®, infringe Purdue s U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoined Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue s petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005.

On February 1, 2006, the Federal Circuit granted Purdue s motion for panel rehearing, vacated the June 7, 2005 decision of the district court, and remanded to the district court for further proceedings. The Federal Circuit s decision on rehearing directs the district court to give further consideration to its previous finding of unenforceability due to inequitable conduct. The Federal Circuit also affirmed the district court s finding that Endo s oxycodone extended-release tablets infringe the Purdue patents. The parties have jointly requested that the district court conduct a status hearing to discuss proceedings on the remand.

The company has reviewed the Federal Circuit Court s opinion with counsel and believes that, on remand, the District Court should again find that Purdue s patents are unenforceable due to Purdue s inequitable conduct before the U.S. Patent and Trademark Office. Endo does not currently intend to pursue an en banc rehearing of the Federal Circuit Court s opinion, but rather intends to pursue the remand proceedings in the District Court. In the event of a final, nonappealable adverse determination against it, the company would be required to terminate its sales of its bioequivalent version of OxyContin®. We can make no prediction as to how or when the District Court will rule on remand or whether Purdue will appeal again in the event we are successful on remand.

In the event that there is a final nonappealable judgment that Purdue s patents are valid and enforceable, Endo could face substantial liability for patent infringement and be obligated to pay Purdue damages in an amount to be determined by the District Court. Damages may be calculated based on profits that Purdue may have lost to Endo s sales of its generic OxyContin for the period the company sold the product, a reasonable royalty, and/or a variety of other legal theories, together with pre- or post-judgment interest on any such damages award. Although there can be

no assurance, the company believes that it would be able to fund the payment of these damages without materially adversely affecting the operations of its business, including its acquisition and licensing strategy. The outcome of litigation is always uncertain, as are the imposition and level of damages. However, after consultation with counsel, the company believes that it is unlikely that Purdue would be awarded enhanced damages, such as treble damages.

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On June 8, 2005, EPI filed a complaint against Purdue Pharma L.P., the Purdue Frederick Company, the Purdue Pharma Company, Ivax Corporation and Ivax Pharmaceuticals, Inc. (collectively, Defendants) in the Superior Court of the Judicial District of Norwalk-Stamford Connecticut, alleging a violation of the Connecticut Unfair Trade Practices Act. Specifically, EPI claimed that the Defendants have engaged in unfair trade practices by launching an authorized generic version of Purdue s OxyContin® on the heels of the Federal Circuit s ruling that Purdue obtained its patents on OxyContin® through inequitable conduct. EPI sought temporary and permanent injunctions enjoining Defendants from marketing or selling their authorized generic OxyContin® during Endo s 180-day market exclusivity period, as well as compensatory damages, punitive damages, and attorneys fees incurred in connection with the action. Defendants removed the case to the U.S. District Court for the District of Connecticut on July 1, 2005. In addition, Purdue filed a Motion to Dismiss, on July 1, 2005, and Ivax filed a Motion to Dismiss on July 8, 2005. EPI filed a Motion for Remand on August 5, 2005. On September 19, 2005, the District of Connecticut denied EPI s motion for remand. On the same date, EPI voluntarily dismissed the complaint without prejudice to refiling.

Litigation similar to that described above may also result from products we currently have in development, as well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

Linda Serafin, et al. v. Purdue Pharma L.P., et al., No. 103031/04 (Supreme Court of the State of New York, County of New York)

On February 27, 2004, EPI was named, along with three other pharmaceutical companies, a hospital, and a doctor, as a defendant in a lawsuit filed by Linda Serafin and Michael Serafin in the Supreme Court of the State of New York, County of New York. The complaint alleged that EPI and another defendant manufactured oxycodone, OxyContin® and/or Percocet®. The complaint alleged that the defendants failed to adequately warn about the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs sustained injury. Plaintiffs counsel agreed to dismiss EPI, along with the other pharmaceutical manufacturer companies, with prejudice. EPI was dismissed without any payment or other remuneration from the Company. The Stipulation of Dismissal with respect to EPI was filed on January 17, 2006.

Litigation similar to that described above may also be brought by other plaintiffs in other jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

Pricing Litigation

A number of cases, brought by local and state government entities, are pending that allege generally that EPI and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. These cases generally seek damages, treble damages, disgorgement of profits, restitution and attorneys fees.

The federal court cases have been or are in the process of being consolidated in the United States District Court for the District of Massachusetts under the Multidistrict Litigation Rules as *In re: Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456*. The following previously reported cases are pending in MDL 1456 and have been or will likely be consolidated into one consolidated complaint: *City of New York v. Abbott Laboratories, Inc., et al.*; *County of Albany v. Abbott Laboratories, Inc., et al.*; *County of Allegany v. Abbott Laboratories, Inc., et al.*; *County of Broome v. Abbott Laboratories, Inc., et al.*; *County of Cattaraugus v. Abbott Laboratories, Inc., et al*; *County of Cayuga v. Abbott Laboratories, Inc., et al.*; *County of Chautauqua v. Abbott Laboratories, Inc., et al.*; *County of Chenango v. Abbott Laboratories, Inc., et al.*; *County of Columbia v. Abbott Laboratories, Inc., et al.*; *County of Cortland v. Abbott Laboratories, Inc., et al.*; *County of Dutchess v. Abbott Laboratories, Inc., et al.*; *County of Essex v. Abbott Laboratories, Inc., et al.*; *County of Fulton v. Abbott Laboratories, Inc., et al.*; *County of Genesee v. Abbott Laboratories, Inc., et al.*; *County of Greene v. Abbott Laboratories, Inc., et al.*; *County of Herkimer v. Abbott Laboratories, Inc., et al.*; *County of Jefferson v. Abbott Laboratories, Inc., et al.*; *County of Lewis v. Abbott Laboratories, Inc., et al.*; *County of Madison v.*

Abbott Laboratories, Inc., et al.; *County of Monroe v. Abbott Laboratories, Inc., et al.*; *County of Niagara v. Abbott Laboratories, Inc., et al.*; *County of Oneida v. Abbott Laboratories, Inc., et al.*; *County of Onondaga v. Abbott Laboratories, Inc., et al.*; *County of Ontario v. Abbott Laboratories, Inc., et al.*; *County of Orleans v. Abbott Laboratories, Inc., et al.*; *County of Putnam v. Abbott Laboratories, Inc., et al.*; *County of Rensselaer v. Abbott Laboratories, Inc., et al.*; *County of Rockland v. Abbott Laboratories, Inc., et al.*; *County of St. Lawrence v. Abbott Laboratories, Inc., et al.*; *County of Saratoga v. Abbott Laboratories, Inc., et al.*; *County of Schuyler v. Abbott Laboratories, Inc., et al.*; *County of Seneca v. Abbott Laboratories, Inc., et al.*; *County of Steuben v. Abbott Laboratories, Inc., et al.*; *County of Suffolk v. Abbott Laboratories, Inc., et al.*; *County of Tompkins v. Abbott Laboratories, Inc., et al.*; *County of Warren v. Abbott*

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Laboratories, Inc., et al.; *County of Washington v. Abbott Laboratories, Inc., et al.*; *County of Wayne v. Abbott Laboratories, Inc., et al.*; *County of Westchester v. Abbott Laboratories, Inc., et al*; and *County of Yates v. Abbott Laboratories, Inc., et al.*

Three additional New York counties represented by the same law firm as the counties described above filed lawsuits under seal in federal district court. Those lawsuits are: County of Chemung v. Abbott Laboratories, Inc., et al., filed in December 2005 in the United States District Court for the Western District of New York; County of Ulster v. Abbott Laboratories, Inc., et al., filed in January 2006 in the United States District Court for the Northern District of New York; and County of Wyoming v. Abbott Laboratories, Inc., et al., filed in December 2005 in the United States District Court for the Western District of New York. It is expected that these cases will be transferred to MDL 1456 and will join the cases described above in a consolidated complaint.

One previously reported case filed in state court and removed to federal court has been remanded back to state court: *County of Erie v. Abbott Laboratories, Inc., et al.*

There is a previously reported case pending in state court in Alabama against EPI and numerous other pharmaceutical companies: *State of Alabama v. Abbott Laboratories, Inc., et al.,* filed in January 2005 in the Circuit Court of Montgomery County.

There is a previously reported case pending in Mississippi against EPI and numerous other pharmaceutical companies: *State of Mississippi v. Abbott Laboratories, Inc., et al.*, filed in October, 2005 in the Chancery Court of Hinds County, Mississippi.

The Company intends to contest all of these cases vigorously. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against the Company.

Other Legal Proceedings

In addition to the above proceedings, we are involved in, or have been involved in, arbitrations or various other legal proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these claims and other proceedings. Currently, we are not involved in any arbitration and/or other legal proceeding that we expect to have a material effect on our business, financial condition, results of operations or cash flows.

Leases

We lease office and laboratory facilities under certain noncancelable operating leases that expire through January 2015. These leases are renewable at our option. Our capital leases primarily consist of leased automobiles. A summary of minimum future rental payments required under capital and operating leases as of December 31, 2005 is as follows (in thousands):

	Capital Leases	Operating Leases
2006	2,881	2,873
2007	1,592	2,727
2008	460	2,733
2009	8	2,740
2010		2,942
Thereafter		8,089
Total minimum lease payments	$ 4,941	$ 22,104
Less: Amount representing interest	573	
Total present value of minimum payments	$ 4,368	
Less: Current portion of such Obligations	2,591	
Long-term capital lease obligations	$ 1,777	

Rent expense incurred under operating leases was $3.1 million, $2.5 million and $2.0 million for the years ended December 31, 2005, 2004 and 2003, respectively.

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13. Savings and Investment Plan

On September 1, 1997, we established a defined contribution Savings and Investment Plan covering all employees. Employee contributions are made on a pre-tax basis under section 401(k) of the Internal Revenue Code (the Code). We match up to six percent of the participants contributions subject to limitations under section 401(k) of the Code. Participants are fully vested with respect to their own contributions. Participants are fully vested with respect to our contributions after three years of continuous service. Contributions by us amounted to $3.1 million, $2.2 million, and $1.4 million for the years ended December 31, 2005, 2004 and 2003, respectively.

14. Stockholders Equity

Common Stock

Payment of dividends is restricted under terms of the Amended and Restated Credit Agreement.

Preferred Stock

The Board of Directors may, without further action by the stockholders, issue a series of Preferred Stock and fix the rights and preferences of those shares, including the dividend rights, dividend rates, conversion rights, exchange rights, voting rights, terms of redemption, redemption price or prices, liquidation preferences, the number of shares constituting any series and the designation of such series. As of December 31, 2005, no shares of Preferred Stock have been issued.

Pre-Merger Endo Warrants

The warrants issued to the holders of Company common stock prior to the Algos merger received warrants (known as the Pre-Merger Endo Warrants), which were exercisable at an exercise price of $0.01 per share into a specified number of shares of Company common stock. As of December 31, 2002, there were outstanding 71.3 million of these warrants. As the FDA did not approve MorphiDex® before December 31, 2002, these warrants became exercisable. Each of these outstanding 71.3 million warrants were exercisable into 0.416667 shares of common stock of Endo Pharmaceuticals Holdings Inc. All of these warrants were exercised into 29,687,602 shares of common stock at an exercise price of $0.01 per share. The warrants were exercisable until July 8, 2003.

Endo Pharma LLC 1997 Executive and Employee Stock Option Plans and Endo Parma LLC 2000 Supplemental Executive and Employee Stock Option Plans

On November 25, 1997, the Company established the 1997 Employee Stock Option Plan and the 1997 Executive Stock Option Plan (collectively, the 1997 Stock Option Plans). On July 17, 2000, the 1997 Stock Option Plans were amended and restated. The Endo Pharma LLC

1997 Stock Option Plans are these amended and restated 1997 Stock Options Plans and reserved an aggregate of 25,615,339 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 1997 Stock Option Plans expire on August 26, 2007. Upon exercise of these stock options, only currently outstanding shares of common stock of the Company held by Endo Pharma LLC are issued. Exercise of these stock options has not and will not result in the issuance of additional shares in the Company and does not dilute the public stockholders.

Pursuant to the Algos merger and related recapitalization of the Company on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Stock Option Plans were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserved an aggregate of 10,672,314 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expire on August 26, 2007. The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of 10,672,314 stock options to certain employees and members of management. No additional shares of Company common stock have been or will be issued as a result of the exercise of these stock options, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, exercise of these stock options has not and will not result in the issuance of additional shares in the Company and does not dilute the public stockholders.

The shares of Company common stock that individuals receive upon exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

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A summary of the activity under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans from January 1, 2003 through December 31, 2005 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2003	23,766,755	$ 2.71
Granted	10,672,314	$ 2.42
Exercised	(2,466,803)	$ 2.46
Forfeited	(87,240)	$ 2.80
Outstanding, December 31, 2003	31,885,026	$ 2.63
Exercised	(6,854,980)	$ 2.46
Forfeited	(754)	$ 2.42
Outstanding, December 31, 2004	25,029,292	$ 2.68
Exercised	(22,219,680)	$ 2.71
Forfeited	(347)	$ 2.42
Outstanding, December 31, 2005	2,809,265	$ 2.42

The following table summarizes information about stock options outstanding under the Endo Pharma LLC Stock Option Plans at December 31, 2005:

Options Outstanding		
Number Outstanding	Weighted Average Remaining Contractual Life	Exercise Price
2,809,265	20 months	$ 2.42

Of the outstanding Endo Pharma LLC stock options as of December 31, 2005, 1,309,392 shares have vested and are exercisable ratably over service periods of five years and 1,199,898 shares have vested and are exercisable at the end of nine years from the date of grant. The vesting and exercisability of options may be accelerated at the discretion of the Board of Directors or upon the occurrence of certain defined events.

During the year ended December 31, 2003, 4,810,936 Class C Endo Pharma LLC stock options vested upon achievement of certain performance conditions. We recorded a $96.0 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price and the exercise price of the vested stock options.

The Class C Endo Pharma LLC stock options (all of which were vested) became exercisable at the earlier of an exit event, as defined, or January 1, 2006. If the Class C stock options were not exercised by January 1, 2006, they would have expired. Although the Company had considered extending the term of the Class C stock options, following enactment of the 2004 American Jobs Creation Act, an extension of the term of the stock options would result in adverse tax consequences for the option holders. As a result, the Company and Endo Pharma LLC decided to accelerate the exercisability of the Class C stock options to allow approximately 22 million Class C stock options to be exercised before their expiration on January 1, 2006. The exercise of the Class C stock options is expected to generate a significant tax deduction for the Company and create a significant tax sharing payment obligation to Endo Pharma LLC pursuant to the tax sharing agreement (See Note 16). Upon exercise, option holders received shares of Company common stock currently owned by Endo Pharma LLC. Accordingly, no additional shares of Company common stock were issued upon the exercise of the Class C stock options during the year ended December 31, 2005.

Stock options exercisable pursuant to the Endo Pharma LLC 1997 Stock Option Plans as of December 31, 2005 and 2004 were 2,509,290 and 1,958,537, respectively.

Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans

In August 2000, we established the 2000 Stock Incentive Plan. The 2000 Stock Incentive Plan reserves an aggregate of 4,000,000 shares of common stock of the Company for issuance to employees, officers, directors and consultants. The 2000 Stock Incentive Plan provides for the issuance of stock options, restricted stock, stock bonus awards, stock appreciation rights or performance awards. In May 2004, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2004 Plan is 4,000,000 shares. The 2004 Plan provides for the grant of stock options, stock appreciation rights, shares of restricted stock, performance shares, performance units or other share-based awards that

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may be granted to executive officers and other employees of the Company, including officers and directors who are employees, to non-employee directors and to consultants to the Company. As of December 31, 2005, only stock options have been awarded under both plans. Stock options granted under the 2000 and 2004 Stock Incentive Plans generally vest over four years, except in the case of certain change of control events as defined in the Plans, and expire ten years from the date of grant. Unlike the stock options granted under the Endo Pharma LLC Stock Option Plans, the exercise of the stock options granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans will dilute our public stockholders. As of December 31, 2005, stock options outstanding under the 2000 and 2004 Stock Incentive Plan were vested and exercisable into 1,430,058 shares, at a weighted average exercise price of $11.82. 6,951,179 shares were reserved for future issuance upon exercise of options granted or to be granted under these plans.

A summary of the activity under our 2000 and 2004 Stock Incentive Plans from January 1, 2003 through December 31, 2005 is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2003	1,985,223	$ 8.82
Granted	1,441,290	$ 15.90
Exercised	(17,714)	$ 8.74
Forfeited	(78,620)	$ 9.95
Outstanding, December 31, 2003	3,330,179	$ 11.86
Granted	981,806	$ 17.61
Exercised	(86,248)	$ 8.96
Forfeited	(238,191)	$ 15.94
Outstanding, December 31, 2004	3,987,546	$ 13.09
Granted	392,807	$ 22.13
Exercised	(944,859)	$ 10.78
Forfeited	(136,064)	$ 14.40
Outstanding, December 31, 2005	3,299,430	$ 14.78

The weighted average, grant date fair value per option granted was $11.66, $9.83 and $9.54 for options granted during the years ended December 31, 2005, 2004 and 2003, respectively.

The following table summarizes information about stock options outstanding under our 2000 and 2004 Stock Incentive Plans at December 31, 2005:

2000 and 2004 Stock Incentive Plans Options Outstanding

Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Exercisable Weighted Average Exercise Price	Range of Exercise Prices
623,595	6.1	$ 8.44	525,528	$ 8.31	$ 6.47 -$ 9.17
416,927	6.3	$ 9.33	308,577	$ 9.34	$ 9.18 - $ 9.40
782,000	7.5	$ 14.60	357,332	$ 14.47	$ 9.41 - $15.24
637,666	8.5	$ 16.32	103,732	$ 16.46	$ 15.25-$16.47
839,242	8.8	$ 21.18	134,889	$ 20.63	$ 16.48- $29.99

15. Earnings Per Share

The following is a reconciliation of the numerator and denominator of basic and diluted earnings per share for the years ending December 31, 2005, 2004 and 2003 (in thousands, except per share data):

	2005	2004	2003
Numerator:			
Net income available to common stockholders	$ 202,295	$ 143,309	$ 69,790
Denominator:			

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For basic per share data weighted average shares	132,242	131,805	128,417
Effect of dilutive stock options	1,047	913	4,022
For diluted per share data weighted average shares	133,289	132,718	132,439
Basic earnings per share	$ 1.53	$ 1.09	$ 0.54
Diluted earnings per share	$ 1.52	$ 1.08	$ 0.53

Anti-dilutive securities were 15,698, 70,629 and 359,475 for 2005, 2004 and 2003, respectively and have not been included above. Stock options exercisable pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans do not result in the issuance of additional shares of the Company and are only exercisable, after the achievement of various conditions, into common stock of the Company held by Endo Pharma LLC.

16. Related Party Transactions

Tax Sharing Agreement. On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Endo Pharma LLC is a limited liability company that held approximately 15% of our common stock at December 31, 2005, in which affiliates of Kelso & Company and certain members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC have been and will delivered. Because Endo Pharma LLC, and not us, has been and will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of December 31, 2005, approximately 32.7 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of December 31, 2005, approximately $669 million), which is estimated to result in a tax benefit amount of approximately $257 million. Under the tax sharing agreement, we are required to pay this $257 million, $56 million of which has already been paid as of December 31, 2005, to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto. Additionally, as part of the tax sharing agreement, Endo Pharma LLC will reimburse us for the after-tax employer payroll taxes paid by us as a result of the exercise of the 32.7 million options discussed above. We have paid approximately $9.9 million in employer payroll taxes, of which Endo Pharma LLC will reimburse us for approximately $6.1 million, which represents the after-tax employer payroll tax expensed by us for the periods from 2001 through 2005.

On April 30, 2004, the tax sharing agreement was amended to provide for a specific schedule upon which payments currently contemplated by the tax sharing agreement would be made. The amended tax sharing agreement provides that the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i) 50% of the estimated amount shall be paid within 15 business days of our receipt from our independent registered public accounting firm of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return.

In 2004, we paid $13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. Since 6.6 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offerings on August 9, 2004 and November 29, 2004, at prices of $17.46 and $20.02, respectively, with a weighted average exercise price of $2.44, and an assumed tax rate of 38.7%, we were obligated to pay Endo Pharma LLC a tax benefit of approximately $41 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and other Endo Pharma LLC stock option exercises in 2004, aggregating $21.4 million, was due and was paid within 15 business days of the date we received an opinion on our audited 2004 financial statements from our

independent registered public accounting firm and the remaining fifty percent of the tax benefit amount attributable to 2004 was due within 30 business days of the date on which we filed our 2004 tax return with the Internal Revenue Service (which occurred in September 2005) and approximately $21.4 million was paid in October 2005 to satisfy the tax sharing obligations attributable to 2004. As of December 31, 2005, approximately $200.9 million is payable to Endo Pharma LLC related to estimated tax sharing payments that we are obligated to pay which are attributable to 2005. This amount will be offset by the $6.1 million after-tax employer payroll amount discussed above. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders equity in the accompanying financial statements. The estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in the future.

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On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14 and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9, 2004 and November 29, 2004 offerings, which totaled 19 million shares, up to 11 million shares remained eligible for sale by Endo Pharma LLC under this shelf registration statement. On September 2, 2005, we filed another registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission on September 26, 2005. This shelf registration statement, as amended, effectively increased the shares available for sale by Endo Pharma LLC from 11 million shares to up to 33.35 million currently issued and outstanding shares of our common stock. All of the shares available under this registration statement were sold pursuant to an offering on October 12, 2005, as discussed below. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future (See Note 17).

The Class C Endo Pharma LLC stock options (all of which were vested) became exercisable at the earlier of an exit event, as defined, or January 1, 2006. If the Class C stock options were not exercised by January 1, 2006, they would have terminated. Although the Company had considered extending the term of the Class C stock options, following enactment of the 2004 American Jobs Creation Act, an extension of the term of the stock options would result in adverse tax consequences for the option holders. As a result, the Company and Endo Pharma LLC decided to accelerate the exercisability of the Class C stock options to allow approximately 22 million Class C stock options to be exercised before their expiration on January 1, 2006. The exercise of the Class C stock options is expected to generate a significant tax deduction for the Company and create a significant tax sharing payment obligation to Endo Pharma LLC pursuant to the tax sharing agreement. Upon exercise, option holders will receive shares of Company common stock currently owned by Endo Pharma LLC. Accordingly, no shares of Company common stock will be issued upon exercise of the Class C stock options.

On October 12, 2005, as part of the sale of 33,350,000 shares of our common stock, approximately 19.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised at a market price of $26.04, with a weighted average exercise price of $2.72, and an assumed tax rate of 38.4%. Since the attributable compensation charge deductions are usable to reduce our taxes in 2005, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately $175 million. Fifty percent of the estimated tax benefit amount attributable to the October 12, 2005 offering and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2005 will be due within 15 business days of the date we receive an opinion on our final audited 2005 financial statements from our independent registered public accounting firm and the remaining tax benefit amount attributable to 2005 is due within 30 business days of the date on which we file our 2005 tax return with the Internal Revenue Service. Additionally, since approximately 2.7 million additional stock options granted under the Endo Pharma LLC stock option plans were exercised during the year ended December 31, 2005, and since the attributable compensation charge deductions are usable to reduce our taxes in 2005, we will be obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately $26 million in 2006. As a result of the significant tax deductions expected to be generated in 2005 from the exercise of the 22.2 million stock options discussed above, we have incurred a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of a portion of prior years payments during 2006. All payments that have been, or will be, made or accrued pursuant to the tax sharing agreement have been, or will be, reflected as a reduction of stockholders equity in our consolidated financial statements. As of December 31, 2005, there are approximately 2.8 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of $2.42 per share and an assumed tax rate of 38.4%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was $30.26 per share, the closing price on December 30, 2005, we would generally be able to deduct, for income tax purposes, compensation of approximately $78 million, which could result in a tax benefit amount of approximately $30 million payable to Endo Pharma LLC in 2007 and beyond.

Settlement of Contingent Obligation. During the year ended December 31, 2005, the Company reached an agreement with an individual to compensate him a total of $2 million for past services rendered to the Company. This agreement was finalized in May 2005, and the $2 million has been recorded in selling, general and administrative expenses during the year ended December 31, 2005. Endo Pharma LLC made these payments totaling $2 million on behalf of the Company, and they have been treated as a capital contribution by Endo Pharma LLC.

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17. Subsequent Events

In January 2006, the Company signed a license agreement with ZARS Pharma that will give it the exclusive North American rights to Synera™ (lidocaine 70 mg and tetracaine 70 mg) topical patch. Under the terms of the agreement, the Company paid ZARS an upfront fee of $11 million, with additional payments of up to approximately $27 million upon achievement of certain commercial milestones, $8 million of which will be due upon the first commercial sale of the product, which is expected in the second half of 2006. The Company will also pay ZARS undisclosed royalties on net sales of Synera™. ZARS is a privately held company based in Salt Lake City, Utah, focused on the development and commercialization of patented technologies that deliver drugs into and across the skin. Synera™ is a topical local anesthetic patch for use on intact skin to provide local dermal anesthesia in children and adults. Approved by the U.S. Food and Drug Administration on June 23, 2005, Synera™ is expected to become commercially available in the second half of 2006.

In January 2006, the Company completed a public offering of 15,000,000 shares of its common stock by certain of its shareholders. All of the shares were already issued and outstanding, except for approximately 40,000 shares representing shares underlying outstanding stock options. Endo Pharma LLC sold the majority of the shares being sold. Certain members of management have an ownership interest in Endo Pharma LLC. Shares were sold by management and certain members of the board of directors of the Company. Following completion of the offering, Endo Pharma LLC held approximately 8.0% of Endo s outstanding common stock.

On February 6, 2006, we announced that our wholly owned subsidiary, Endo Pharmaceuticals Inc., would continue its commercial sales of its bioequivalent version of OxyContin. The company had announced on February 1, 2006 that the Federal Circuit Court of Appeals had vacated its unanimous June 7, 2005 affirmance of the Opinion and Order issued in our favor by the U.S. District Court for the Southern District of New York, which found Purdue had committed inequitable conduct in the U.S. Patent and Trademark Office. The Federal Circuit also affirmed the District Court s finding that, if Purdue s patents are enforceable, our oxycodone extended- release tablets infringe these patents. Further, the Federal Circuit issued a new opinion on February 1, 2006 remanding the case to the same district court for its further consideration as to whether the Purdue patents are unenforceable. (See Note 12 for further discussion).

In February 2006, approximately 1.4 million stock options were granted to employees that will vest over four years, except in the case of certain change of control events as defined in the Plans, and expire ten years from the date of grant. The exercise price of the options granted was equal the closing price on the date of grant.

On March 2, 2006, we amended our license agreement with Noven, effective as of December 31, 2005, to terminate the provisions of the agreement applicable to the generic fentanyl patch product. As part of such amendment, Endo received a right of first negotiation for certain future generic fentanyl patch products that Noven may develop.

18. Quarterly Financial Data (Unaudited)

	Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share data)			
2005(1)				

Net sales	$ 137,754	$ 196,380	$ 245,241	$ 240,789
Gross profit	$ 108,169	$ 154,122	$ 183,842	$ 187,681
Operating income	$ 20,231	$ 77,119	$ 104,726	$ 111,173
Net income	$ 13,815	$ 49,046	$ 66,553	$ 72,881
Net income per share (basic)	$ 0.10	$ 0.37	$ 0.50	$ 0.55
Net income per share (diluted)	$ 0.10	$ 0.37	$ 0.50	$ 0.54
Weighted average shares (basic)	131,871	131,973	132,376	132,736
Weighted average shares (diluted)	132,829	132,929	133,532	133,744

	Quarter Ended			
	March 31,	**June 30,**	**September 30,**	**December 31,**
	(in thousands, except per share data)			
2004(2)				
Net sales	$ 153,489	$ 143,968	$ 160,349	$ 157,294
Gross profit	$ 120,616	$ 115,053	$ 122,146	$ 116,296
Operating income	$ 66,491	$ 50,529	$ 66,148	$ 45,767
Net income	$ 41,174	$ 31,548	$ 41,377	$ 29,210
Net income per share (basic)	$ 0.31	$ 0.24	$ 0.31	$ 0.22
Net income per share (diluted)	$ 0.31	$ 0.24	$ 0.31	$ 0.22
Weighted average shares (basic)	131,779	131,792	131,804	131,842
Weighted average shares (diluted)	132,720	132,789	132,460	132,749

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Quarterly and year to date computations of per share amounts are made independently; therefore, the sum of the per share amounts for the quarters may not equal per share amounts for the year.

(1) Operating income for the year ended December 31, 2005 was impacted by up-front and milestone payments to partners of $20 million in the first quarter, $6.5 million in the third quarter and $0.8 million in the fourth quarter. Operating income for the year ended December 31, 2005 was also impacted by the write-off of the transdermal fentanyl patch inventory and unamortized portion of the license fee of $10.5 million in the third quarter and the recovery of $0.7 million of this write-off in the fourth quarter.

(2) Operating income for the year ended December 31, 2004 was impacted by up-front and milestone payments to partners of $10 million in the second quarter and $3 million in the fourth quarter. Operating income for the year ended December 31, 2004 was also impacted by the termination of a development agreement and the write-off of the unamortized portion of the license fee of $3.8 million in the first quarter.

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Exhibit Index

Exhibit No.	Title
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. (Endo) (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2003 filed with the Commission on May 14, 2003)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, by and among Endo, Endo Pharma LLC (Endo LLC), Kelso Investment Associates V, L.P. (KIA V), Kelso Equity Partners V, L.P. (KEP V) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2003 filed with the Commission on August 14, 2003)
4.1.2	Amendment to Amended and Restated Executive Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEP V and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004) the Commission on July 1, 2003)
4.1.3	Amendment 2 to the Amended and Restated Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of June 5, 2003, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.2 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.2.2	Amendment to Amended and Restated Employee Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEPV and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004)
4.2.3	Amendment 2 to the Amended and Restated Employee Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.3	Employee Stockholders Consent and Release, effective September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Employee Stockholders (as defined therein) signatory thereto (incorporated herein by reference to Exhibit 4.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	Shelf Registration Agreement, dated September 21, 2005, by and between Endo, Endo LLC and certain Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)

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10.2	Shelf Registration Agreement, dated April 30, 2004, between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.2 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.3	Amendment to Shelf Registration Agreement, dated June 10, 2004 between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.3 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.4	[Intentionally Omitted.]
10.5	[Intentionally Omitted.]
10.6	Amended and Restated Tax Sharing Agreement, dated as of April 30, 2004 by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.6 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
10.7	Amended and Restated Credit Agreement, dated as of December 21, 2001, by and between Endo, Endo Pharmaceuticals, the Lenders Party Thereto and JPMorgan Chase Bank (incorporated by reference to Exhibit 10.7 of the Annual Report on Form 10-K for the Year Ended December 31, 2001 filed with the Commission on March 29, 2002)
10.8	Amendment No.1, dated as of April 30, 2004, to the Amended and Restated Credit Agreement dated as of December 21, 2001, among Endo, Endo Pharmaceuticals Inc., the Lenders thereto and JP Morgan Chase. (incorporated herein by reference to Exhibit 10.8 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
10.9	Amendment No.2, dated as of July 13, 2004, to the Amended and Restated Credit Agreement dated as of December 21, 2001, among Endo, Endo Pharmaceuticals Inc., the Lenders thereto and JP Morgan Chase. (incorporated herein by reference to Exhibit 10.9 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
10.10	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. (Endo Pharmaceuticals) and Hind Health Care, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
10.11	[Intentionally Omitted.]
10.12	[Intentionally Omitted.]
10.13	[Intentionally Omitted.]
10.14	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
10.15	Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. (Mallinckrodt) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
10.16	Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt(incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.17	[Intentionally Omitted.]
10.18	Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2002 filed with the Commission on May 14, 2002)

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10.19	Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services Inc.) (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
10.20	Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.22	Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.23	Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.24	Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.25	Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.26	[Intentionally Omitted.]
10.27	[Intentionally Omitted.]
10.28	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28 of the Current Report on Form 8-K dated August 31, 2001)
10.28.1	Letter Agreement, dated as of December 20, 2005, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28.1 of the Current Report on Form 8-K dated December 21, 2005)
10.29	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated August 31, 2001)
10.29.1	Letter Agreement, dated as of December 20, 2005, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29.1 of the Current Report on Form 8-K dated December 21, 2005)
10.30	[Intentionally Omitted.]
10.31	[Intentionally Omitted.]
10.32	[Intentionally Omitted.]
10.33	[Intentionally Omitted.]
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)

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10.35	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated August 31, 2001)
10.35.1	Letter Agreement, dated as of December 20, 2005, by and between Registrant and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35.1 of the Current Report on Form 8-K dated December 21, 2005)
10.36	Amended and Restated Employment Agreement, dated as of December 20, 2005, by and between Endo and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36 of the Current Report on Form 8-K dated December 21, 2005)
10.37	Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.37 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
10.38	[Intentionally Omitted.]
10.39	Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
10.39.1	First Amendment, effective February 1, 2003, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.1 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.39.2	Second Amendment, effective as of December 1, 2004, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.2 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.40	[Intentionally Omitted.]
10.41	Policy of Endo Pharmaceuticals Holdings Inc. Relating to Insider Trading in Company Securities and Confidentiality of Information (incorporated herein by reference to Exhibit 10.41 of the Form 10-Q for the Quarter ended March 31, 2005 filed with the Commission on May 10, 2005)
10.42	Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42 of the Current Report on Form 8-K dated November 14, 2002)
10.42.2	Amendment to Development, Commercialization and Supply License Agreement, dated January 28, 2004, between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.42.3	Amendment No. 2 to the Development, Commercialization and Supply License Agreement, dated November 22, 2004, between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.3 of the Current Report on Form 8-K dated November 29, 2004)
10.42.4	Amendment No. 3 to the Development, Commercialization and Supply License Agreement between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42.4 of the Current Report on Form 8-K dated January 25, 2006)
10.43	Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43 of the Current Report on Form 8-K dated January 8, 2003)

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10.43.2	Amendment to Development and Marketing Strategic Alliance Agreement, dated March 2, 2004, between Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.44	Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company (incorporated by reference to Exhibit 10.44 of the Annual Report on Form 10-K for the Year Ended December 31, 2002 filed with the Commission on March 27, 2003)
10.45	Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.45.1	Amendment to Lease Agreement, dated as of February 16, 2005, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45.1 of the Current Report on Form 8-K dated February 18, 2005)
10.46	License Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.46 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
10.46.1	Termination Agreement, dated as of February 24, 2006, by and between Noven Pharmaceuticals, Inc., a Delaware corporation, and Endo Pharmaceuticals Inc.*
10.47	Supply Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.47 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
10.48	License and Co-Promotion Rights Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48 of the Current Report on Form 8-K dated July 19, 2004)
10.48.1	Co-Promotion Agreement, dated as of July 1, 2005, by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.1 of the Current Report on Form 8-K dated July 8, 2005)
10.48.2	Second Amendment, dated as of December 12, 2005, to the License Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.2 of the Current Report on Form 8-K dated December 29, 2005)
10.48.3	First Amendment, dated as of December 12, 2005, to the Co-Promotion Agreement by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.3 of the Current Report on Form 8-K dated December 29, 2005)
10.49	Loan Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.49 of the Current Report on Form 8-K dated July 19, 2004)
21	Subsidiaries of the Registrant
23	Consent of Independent Registered Public Accounting Firm
24	Power of Attorney
31.1	Certification of the Chairman and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certificate of the Chairman and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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32.2 Certificate of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.